# DEPARTMENT OF SAFETY AND HOMELAND SECURITY

## OFFICE OF THE MARIJUANA COMMISSIONER

Statutory Authority: 4 Delaware Code, Section 1331 (4 **Del.C.** §1331)
4 **DE Admin. Code** 5001

## FINAL

### ORDER

### 5001 Rules of the Office of the Marijuana Commissioner

### SUMMARY OF THE EVIDENCE

1. Title 4, Section 1331 of the Delaware Code authorizes the Office of Marijuana Commissioner ("OMC") to establish regulations necessary to implement Chapter 13.

2. OMC published its proposed revisions to 4 DE Admin. Code 5001 in the *Delaware Register of Regulations* on January 1, 2026, in 29 **DE Reg.** 590 (01/01/26). A written comment period was held open for thirty days, through February 2, 2026.

3. OMC's purpose in revising the regulation is to: add a definition for "financial interest" to clarify what constitutes a financial interest in a marijuana establishment; implement changes to Section 3.0 Licensing and 4.0 Application Process and Issuance of Licenses to clarify the types of licenses available; implement changes to Section 8.3 Marijuana product package size to align with industry standards; implement changes to Section 10.0 Advertising modifying permissible colors and images on branding and packaging; and implement changes to Section 11.0 Testing and Sampling to update the process for collection and submission of samples and the number of required samples, and to add additional testing options for microbiological contaminants. Other grammar and style changes were made to comply with the *Delaware Administrative Code Drafting and Style Manual*.

4. OMC solicited and requested public comment on the proposed revisions to the regulation in accordance with the Delaware Administrative Procedures Act, 29 **Del.C.** Ch. 101, et. seq., and one written submission containing public comments was submitted. OMC considered the public comments contained in that submission and, as described in more detail below, determined that the proposed changes to add a definition for "financial interest" and to modify product package size (Section 8.3) require additional consideration before implementing any substantive changes.

5. The remaining proposed changes to Sections 3.0 Licensing and 4.0 Application Process and Issuance of Licenses to clarify the types of licenses available, to Section 10.0 Advertising modifying permissible colors and images on branding and packaging, and to Section 11.0 Testing and Sampling to update the process for collection and submission of samples and the number of required samples, and to add additional testing options for microbiological contaminants, require no additional substantive changes and should be adopted as published.

### FINDINGS OF FACT AND CONCLUSIONS

OMC's proposed changes to the regulation fall into two categories: changes intended to clarify existing requirements; and changes intended to modify existing requirements. The clarifying changes included adding a definition for "financial interest" to clarify what constitutes a financial interest in a marijuana establishment, changes to Sections 3.0 Licensing and 4.0 Application Process and Issuance of Licenses to clarify the types of licenses available, and other grammar and style changes to comply with the *Delaware Administrative Code Drafting and Style Manual*. The proposed changes intended to modify existing requirements included changes to Section 8.3 Marijuana product package size to align with industry standards, changes to Section 10.0 Advertising modifying permissible colors and images on branding and packaging, and changes to Section 11.0 Testing and Sampling to update the process for collection and submission of samples and the number of required samples, and to add additional testing options for microbiological contaminants.

OMC received comments on the "financial interest" definition that suggest OMC's proposed definition may be too broad to serve its intended purpose. Thus, OMC intends to revise its proposed definition and re-publish its proposed language in a future publication.

OMC did not receive any public comments on its changes to Sections 3.0 Licensing and 4.0 Application Process and Issuance of Licenses; thus, OMC finds that it is appropriate to adopt the proposed changes to Sections 3.0 and 4.0, as published.

After publication of the proposed changes, OMC determined that its intended changes to the marijuana product package sizes require additional substantive changes beyond those identified in Section 8.3. Therefore, OMC has determined that additional substantive changes to other sections of the regulation must be published before it can implement the intended changes to Section 8.3.

The public comment OMC received on the proposed changes to Section 10.0 Advertising, modifying permissible colors and images on branding and packaging, sought clarification on how the revisions would be implemented, but did not offer commentary indicating substantive issues with the change or proposing any further revisions. Therefore, OMC finds that it is appropriate to adopt the proposed changes to Section 10.0, as published.

Finally, the public comment OMC received regarding the changes to Section 11.0 Testing and Sampling, inquired about the scientific basis for the proposed change and suggested modifying the requirements in a different manner. OMC reviewed and considered the public comment's proposed alternative but finds that the proposed alternative does not adequately address the public safety concern on which this change is founded. Specifically, OMC's change retains the original non-specific contaminant limits thresholds but adds permissible alternative testing options that allows for higher thresholds of certain types of contaminants. Thus, OMC finds that it is appropriate to adopt the proposed changes to Section 11.0 Testing and Sampling, as published.

## STATEMENT OF CLIMATE IMPACT

An assessment of the impact of the proposed revised regulations on the achievement of the State's greenhouse gas emissions reduction target and the State's resiliency to climate change is not practical for this regulation.

## ORDER

**AND NOW this 9th day of February, 2026**, it is hereby ordered that:

1. The proposed regulation revisions to Sections 3.0, 4.0, 10.0, and 11.0 are hereby adopted; and
2. The effective date of this order is 10 days from the date of its publication in the *Delaware Register of Regulations* in accordance with 29 **Del.C.** §10118(g).

**IT IS SO ORDERED.**
**Office of the Marijuana Commissioner**
**Joshua Sanderlin, Commissioner**

## 5001 Rules of the Office of the Marijuana Commissioner

### 1.0 General Provisions

1.1 Authority. This regulation is promulgated by the Office of the Marijuana Commissioner pursuant to its authority in the Delaware Marijuana Control Act, 4 **Del.C.** Chapter 13.

1.2 Purpose and Construction. This regulation establishes the standards for issuing marijuana establishment licenses, social equity businesses, and a retail sales tax. They also include a system for inspection, tracking, packaging, and testing marijuana to ensure marijuana products are safe. This regulation shall be liberally construed and applied to promote their underlying purpose of protecting the public's safety, health, and well-being.

1.3 Severability. In the event any particular clause or section of this regulation should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full effect.

1.4 This regulation shall be referred to as the "Regulations of the Office of the Marijuana Commissioner."

### 2.0 Definitions

The definitions set forth in 4 **Del.C.** §1302 are hereby adopted and incorporated by reference in this regulation. The following words and terms, when used in this regulation, should have the following meaning:

"**Act**" means the Delaware Marijuana Control Act, 4 **Del.C.** Ch. 13.

"**Agent**" means those persons included in 4 **Del.C.** §1347.

"**Applicant**" means any person applying for a Delaware marijuana business license.

"**Branding**" means the promotion of a marijuana establishment's brand through the publication of the business name, logo, or other unique design features.

"**Business days**" means any day of the week during which normal business operations are conducted, and does not include Saturday and Sunday, or State-recognized holidays.

"**Business license**" means a license issued by the Department of Finance and required by Title 30 of the Delaware Code to carry on a trade or business.

"**Certificate of Analysis**" means the report prepared for the marijuana establishment requesting testing regarding the analytical testing performed and results obtained by the marijuana testing facility.

"**Certificate of Tax Clearance**" means a tax certificate issued by Revenue, which certifies that, according to the Revenue's records, as of the date of the certificate, the taxpayer has filed all required State of Delaware tax returns and paid all tax reported thereon, including penalties and interest if applicable, and does not currently owe any tax to the Revenue.

"**Commissioner**" means the person appointed by the Governor and confirmed by the Senate who serves as the Marijuana Commissioner for the State, as defined in 4 **Del.C.** §1302(2).

"**Consumer**" means an individual 21 years of age or older who purchases marijuana, marijuana products, or marijuana accessories for personal use by the individual or other individuals 21 years of age or older, but not for resale to others.

"**Consumer product**" means any product not containing marijuana that is marketed and sold to consumers.

"**Control**" means the decision-making authority over the management, operations, or policies that guide a business, or the authority over the operation of the technical aspects of a business.

"**Delaware Taxpayer Portal**" means Revenue's website for tax accounting administration and tax return and remittance filing located at https://tax.delaware.gov.

"**Deli style dispensing**" means marijuana flower sold to consumers that is not pre-packaged prior to sale.

"**Department**" means the Department of Safety and Homeland Security.

"**Division**" means the Division of Alcohol and Tobacco Enforcement.

"**DNREC**" means the Delaware Department of Natural Resources and Environmental Control.

"**Edible marijuana product**" means a marijuana product intended to be consumed orally and swallowed, including gummy candies ("gummies"), baked goods, hard candies, chocolates, or films.

"**Employee**" means an individual hired directly and paid wages by a marijuana establishment. It does not include volunteers, or contractors or agents who are compensated by other entities.

**[~~"Financial interest" means any direct or indirect ownership or control in a marijuana establishment, including equity ownership, profit or revenue sharing interest, control rights, and de facto ownership. For purposes of this definition, financial interest does not include employment compensation in the form of salary or wages, contracts for the sale of goods or services at fair market value, or holdings of less than 5% in a publicly traded company. Equity ownership means holding any legal or beneficial ownership interest, however small, in an entity. Profit or revenue sharing interest means any right to receive a share of a marijuana establishment's gross revenue, net revenue, or profits, whether through contract, management agreement, consulting agreement, or otherwise. Control rights means any arrangement that provides the ability to influence or direct the management, operations, or policies of the establishment, including through voting rights, veto rights, or contractual provisions. De facto ownership means any relationship or agreement, formal or informal, that effectively allows a person or entity to exercise ownership-like rights or reap the economic benefits of ownership, regardless of whether such interest is recorded in the entity's governing documents.~~]**

"**Flowering plant**" means a marijuana plant from the time it exhibits the first signs of sexual maturity through harvest, which includes budding.

"**Inhalable marijuana product**" means a marijuana product intended to be consumed through inhalation of smoke or vapor, including ~~but not limited to~~ marijuana flower and marijuana concentrate.

"**Kief**" means the sand-like excess plant material and loose trichomes resulting from the grinding and sifting of dried and cured marijuana flower; also referred to as "dry sieve."

"**Marijuana**" means as defined in 16 **Del.C.** §4701.

"**Marijuana beverage**" means a marijuana product in a liquid form intended to be consumed orally and swallowed. Marijuana beverage includes single-serving marijuana beverages and multi-serving marijuana beverages. Marijuana beverages do not include tinctures.

"**Marijuana concentrate**" means any product created when marijuana flower is refined into a more potent and purer product. This umbrella term includes any type of hash (water hash, pressed hash), dry sieve (kief), as well as hash oils (CO2 oil, shatter, butter/budder, wax, resin/live resin, and rosin/live rosin) and indicates that these products are a concentrated form of marijuana, carrying a higher potency.

"**Marijuana flower**" means the fresh, cured, or dried flower of the marijuana plant as defined in 16 **Del.C.** §4701. "Marijuana" as it is defined in this regulation includes marijuana flower.

"**Marijuana waste**" means any organic waste containing marijuana that is generated through the cultivation, manufacturing, or destruction process of marijuana plants, marijuana, or marijuana products.

"**Marketing layer**" means the outermost layer of a packaged product for retail sale, which is most predominantly apparent and visible. If the retail package consists of only a single layer, then the outer surface of the container is the marketing layer.

"**Medical marijuana program card**" means a registry identification card issued pursuant to 16 **Del.C.** §4909A.

"**Mother plant**" means a female marijuana plant that is cultivated and used only for the purposes of producing clones, by keeping the plant in a vegetative, non-sexually mature state.

"**Multi-serving marijuana beverage**" means a marijuana product in a liquid form intended to be consumed orally through multiple servings. Marijuana beverages do not include tinctures.

"**Neon colors**" means extremely bright versions of primary or secondary colors intended to attract attention.

"**Non-consumable product**" means any product offered for sale by a marijuana establishment that is not intended for human consumption, including clothing, storage containers, rolling papers, or other marijuana accessories.

"**Ownership interest**" means a direct or indirect equity interest in a marijuana establishment, including in its shares or stock.

"**Personnel**" means any employee, agent, or volunteer conducting activities on behalf of a marijuana establishment.

"**Premises**" means the physical facility or property owned and operated by a marijuana establishment.

"**Pre-roll**" means manufactured marijuana flower that is rolled into a marijuana cigarette by a marijuana product manufacturing facility.

"**Qualifying Patient**" means an individual who meets the qualifications to receive a medical marijuana program card.

"**Responsible person**" means each officer or employee, or a member, officer, or employee of a pass-through entity, as defined in §1601 of Title 30 of the Delaware Code, who, as an officer, employee, or member of a marijuana establishment has any control over the marijuana establishment's finances or is responsible for filing the marijuana establishments Retail Marijuana Tax form, or collecting, accounting for, or remitting payment for the marijuana establishment's retail marijuana tax.

"**Retail area**" means the area of a retail marijuana store where marijuana, marijuana products, and marijuana accessories are offered for sale.

"**Retail Marijuana Tax**" means the tax imposed by 4 **Del.C.** §1382(b).

"**Retail Marijuana Tax Form**" means the form prescribed by Revenue to calculate the Retail Marijuana Tax due to the State.

"**Revenue**" means the Delaware Division of Revenue, a division of the Delaware Department of Finance.

"**Seed-to-sale tracking system**" means the is the software system developed and maintained approved by the Commissioner to track and maintain records across marijuana supply chain activities.

"**Shake**" means the excess leaf, flower, or stem material removed from marijuana plants during the harvest and manufacturing processes.

"**Single-serving marijuana beverage**" means a marijuana product in a liquid form intended to be consumed orally through a single serving. Marijuana beverages do not include tinctures.

"**Tincture**" means a liquid mixture created from a concentrated extract of marijuana.

"**Topical marijuana product**" means a mixture or extract of marijuana made into a balm, lotion, ointment, or rubbing alcohol solution, that is intended to be consumed in a transcutaneous manner.

"**Transdermal marijuana product**" means a marijuana product intended to be applied to the skin, whereby the marijuana can be consumed in a transcutaneous manner. Transdermal marijuana products include stick-on patches.

"**Transport manifest**" means a record, either paper or electronic, required by the Commissioner for the transfer of any marijuana or marijuana product from 1 licensed facility to another licensed facility, including for the purposes of testing.

"**Trim**" means the same as shake.

"**Universal symbol**" means the symbol developed by the Commissioner to be placed on every marijuana product intended for sale, for purposes of identifying the product as regulated and product and sold by a licensed marijuana business.

"**Waiting area**" means the area of a retail marijuana store where customers enter the facility, have their identification and age verified, and where marijuana, marijuana products, and marijuana accessories are not present for sale.

"**Water activity**" means a measure of the quantity of water in marijuana or a marijuana product that is available, and therefore capable of, supporting bacteria, yeasts, and fungi.

**28 DE Reg. 317 (10/01/24)**
**29 DE Reg. 221 (09/01/25)**

## 3.0 Licensing

3.1 Open licenses. The Commissioner may issue the following 4 types of open licenses:

3.1.1 Retail marijuana store license pursuant to 4 **Del.C.** §1332.

3.1.2 Marijuana testing facility license pursuant to 4 **Del.C.** §1333.

3.1.3 Marijuana cultivation facility license pursuant to 4 **Del.C.** §1334.

3.1.4 Marijuana product manufacturing license pursuant to 4 **Del.C.** §1335.

3.2 Social equity license. The Commissioner may issue the following 4 types of social equity licenses:

3.2.1 Retail marijuana store license pursuant to 4 **Del.C.** §1343(e)(1).

3.2.2 Marijuana testing facility license pursuant to 4 **Del.C.** §1343(e)(2).

3.2.3 Marijuana cultivation facility license pursuant to 4 **Del.C.** §1343(c).

3.2.4 Marijuana product manufacturing license pursuant to 4 **Del.C.** §1343(d).

3.2.5 To apply for a social equity license, an individual must meet 1 of the criteria listed in 4 **Del.C.** §1336.

3.3 Microbusiness license. The Commissioner may issue the following 2 types of microbusiness licenses:

3.3.1 Marijuana cultivation facility license pursuant to 4 **Del.C.** §1343(c).

3.3.2 Marijuana product manufacturing license pursuant to 4 **Del.C.** §1343(d).

3.3.3 To hold a microbusiness license, an individual must meet the criteria listed in 4 **Del.C.** §1340.

## 4.0 Application Process and Issuance of Licenses

4.1 Application requirements

4.1.1 An applicant must submit an application for a license on the form made available by the Commissioner.

4.1.2 An applicant may not apply for, may not be issued, and may not renew any license that would result in the applicant, or a person with a financial interest in that application or license under Title 4 of the Delaware Code, owning or operating more than 1 marijuana establishment of the same license type ~~(cultivation, manufacture, retail, or testing)~~ in a single county.

4.1.2.1 An applicant is not prohibited from applying for and being issued or renewed more than 1 license in a single county, provided that each license is of a different license type.

4.1.2.2 This section does not apply to converted medical licenses.

4.1.3 The Commissioner does not require an applicant to obtain or own any property or facility to operate a marijuana business prior to conditional licensing.

4.1.4 The Commissioner may verify an applicant's status as a social equity applicant at any time prior to entry into the lottery and require the applicant to submit supporting documentation. Any information an applicant submits in support of their social equity status is considered part of the application and is subject to verification by the Commissioner.

4.2 Minimum qualifications

4.2.1 The Commissioner shall determine whether a submitted application meets the minimum qualifications for the lottery by reviewing the applicant's materials required by 4 **Del.C.** §1331. The Commissioner also requires that:

4.2.1.1 Applicants provide a description of their plan to comply with guidance pertaining to marijuana issued by the Financial Crimes Enforcement Network under the Bank Secrecy Act (31 U.S.C. § 5311 et seq.), which may be demonstrated by submitting letters regarding the applicant's banking history from banks or credit unions that certify they are aware of the business activities of the applicant in any state where the applicant has operated a business related to personal use or medical marijuana. An applicant who does not submit the information about a plan of compliance with the Bank Secrecy Act shall not be disqualified from consideration.

4.2.1.2 For marijuana cultivation facility license and marijuana product manufacturing facility license applicants only: quality assurance plan with written policies and procedures for a comprehensive quality assurance program.

4.2.1.3 The Commissioner may require an applicant, or any individual or entity that holds an ownership interest in or control of the applicant, to complete an attestation demonstrating the applicant meets the requirements for the license established in 4 **Del.C.** §1331.

4.2.1.4 Additional minimum qualifications may be established by the Commissioner and published on its website at https://omc.delaware.gov.

4.2.2 Applicants must remit a nonrefundable application fee as set forth in 4 **Del.C.** §§1331, 1337, and 1341. The Commissioner may adjust the application fees annually for inflation.

4.2.3 The Commissioner may determine that a completed social equity license application may be entered into an open license lottery for the applicable license type without payment of any additional application fees.

4.3 Application review process

4.3.1 The Commissioner will announce the application period at least 10 business days prior to the acceptance of applications. The announcement will include:

4.3.1.1 Types and number of licenses available; and

4.3.1.2 The date the application period begins.

4.3.2 The Commissioner will accept applications for 30 calendar days.

4.3.3 The responsibility for demonstrating the minimum qualifications set forth in Title 4 of the Delaware Code and in this regulation rests on the applicant.

4.3.4 The Commissioner may deny an application for any of the reasons listed in 4 **Del.C.** §1354 and where the application:

4.3.4.1 Is incomplete in any material detail;

4.3.4.2 Contains a material misstatement, omission, misrepresentation, or untruth;

4.3.4.3 Does not meet the minimum qualifications for the license type;

4.3.4.4 Is not submitted by the established deadline; or

4.3.4.5 Fails to provide additional information requested by the Commissioner.

4.3.5 The Commissioner may award fewer licenses than authorized under law in any licensing round if there are an insufficient number of qualified applicants.

4.3.6 The Commissioner will notify all applicants by email whether they met the minimum qualifications and will be placed in the lottery.

4.4 Lottery

4.4.1 Applicants determined by the Commissioner to meet the minimum qualifications will be entered into a lottery. The lottery will be conducted in an impartial and random manner, with the format of the lottery being determined by the Commissioner.

4.4.2 No more than 10 business days following the lottery, the Commissioner will inform all applicants by email whether they were selected for the lottery.

4.4.3 The Commissioner may request any additional information or supporting documentation from an applicant selected in the lottery necessary to verify aspects of the application, including additional information and supporting documentation related to the ownership and control of the applicant.

4.4.4 The Commissioner may deny issuing a conditional license or an active license to an applicant selected in the lottery if:

4.4.4.1 The applicant fails to provide any additional information or supporting documentation within 10 business days of being notified that a correction needs to be made; or

4.4.4.2 Additional information or supporting documentation submitted by the applicant demonstrates the applicant is not eligible for a conditional or active license.

4.5 Selected applicant and supplemental license application requirements

4.5.1 A selected applicant must complete a supplemental license application in a format prescribed by the Commissioner.

4.5.2 Selected applicants are granted a period of 30 days from the date of notification of selection from the Commissioner to complete a supplemental license application and pay applicable licensing fees.

4.5.3 A selected applicant is required to:

4.5.3.1 Undergo a criminal background check in accordance with 4 **Del.C.** §1347;

4.5.3.1.1 Applicants must follow all criminal history records check guidance provided by the Commissioner, including fingerprinting and state and federal criminal history records checks;

4.5.3.1.2 For applicants that are business entities, fingerprinting and criminal history record checks are required for every owner, officer, director, and employee; and

4.5.3.1.3 The applicant is responsible for all costs associated with fingerprinting and criminal history record checks.

4.5.3.2 Undergo a comprehensive financial background investigation under direction of the Commissioner and authorize the release of financial and background information from all financial institutions, fiduciaries, and other entities, exempting them from any contractual, statutory, or common law confidentiality obligations, to aid in assessing the applicant's capability to operate a marijuana establishment;

4.5.3.3 Submit a Certificate of Tax Clearance for responsible persons;

4.5.3.4 Describe all civil litigation or any settled or closed legal action over the past 3 years to which the applicant, its parent, affiliate, holding, or any subsidiary is or was a party whether in this state or in another jurisdiction.

4.5.3.5 Disclose whether the applicant or any affiliate, intermediary, subsidiarity or holding company ever had any license application, license, permit, or other authorization issued by a government agency in this state or any other jurisdiction denied, suspended, or revoked in the last 10 years.

4.5.3.6 Execute waiver provided by the Commissioner to permit any governmental authority in any jurisdiction to share with the Commissioner and the Division all data the selected applicant has previously provided to other jurisdictions in connection with a marijuana-related license, as well as any information those jurisdictions have gathered during their investigations of the selected applicant;

4.5.3.7 Submit verification provided by the Commissioner for any information or supporting documentation submitted with the application;

4.5.3.8 Provide the municipality or county within which the selected applicant intends to operate; and

4.5.3.9 Provide any additional information required by the Commissioner.

4.5.4 If a selected applicant fails to meet the requirements in subsection 4.5.3 of this regulation within the 30-day period, the Commissioner may extend this period provided that the applicant demonstrates a good faith effort towards completion. Should the Commissioner deny the extension request, or the selected applicant remains unable to meet the requirements outlined in subsection 4.5.3 of this regulation, the Commissioner is authorized to cancel the application.

4.5.5 The applicable licensing fees are set forth in 4 **Del.C.** §§1331-1334, 1337, and 1341, and are payable to the Office of the Marijuana Commissioner biennially.

4.5.6 Upon successful completion and approval of the application and payment of licensing fees, the applicant will be granted a conditional license pursuant to 4 **Del.C.** §1345.

4.5.7 Prior to the issuance of a conditional license, the applicant may not:

4.5.7.1 Purchase, possess, cultivate, manufacture, or sell marijuana or marijuana products;

4.5.7.2 Transfer any ownership interest that causes a change in the individual or entity that holds the controlling ownership interest;

4.5.7.3 Transfer control; or

4.5.7.4 Transfer an ownership interest that causes the conditional social equity licensee to no longer meet the social equity applicant definition.

4.6 Issuance of conditional license

4.6.1 Any applicant who receives a conditional license must identify a physical location for the licensed premises and become operational within 18 months from the date the conditional license is granted. The proposed licensed premises must be approved by the Commissioner.

4.6.2 If the applicant is unable to begin operations meeting all criteria established by the Commissioner within 18 months of issuance of the conditional license, the Commissioner may extend the period to become operational if the conditional licensee demonstrates good faith efforts to begin operations. If the Commissioner denies the extension of the conditional license or the licensee is unable to become operational, the Commissioner must rescind the conditional license.

4.7 Termination of a conditional license. The Commissioner may terminate a conditional license if a conditional licensee or any individual or entity included in the application:

4.7.1 Has been convicted of or pleaded nolo contendere to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have conviction or plea set aside;

4.7.2 Fraudulently or deceptively attempts to obtain a license;

4.7.3 Is ineligible to hold an ownership interest in or control of a business licensed under subsection 4.1.2;

4.7.4 Fails to reveal any material fact pertaining to the temporary licensee's qualification for a license;

4.7.5 Fails to submit a complete supplemental license application;

4.7.6 Fails to convert to an active licensee;

4.7.7 Violates this regulation;

4.7.8 Is not registered or in good standing with the Division of Corporations; or

4.7.9 Has taxes in arrears in any jurisdiction.

4.8 Issuance of an active license. A conditional license will convert to an active license as provided in 4 **Del.C.** §1346. The Commissioner also requires:

4.8.1 Submission and subsequent approval of final safety, security, theft or diversion, and operations plans by the Commissioner;

4.8.2 Payment of any fees or costs associated with obtaining a background check;

4.8.3 Submission of an attestation signed by a bona fide labor organization stating that the licensee has entered into a labor peace agreement with the bona fide labor organization;

4.8.4 Submission of a form, provided by the Commissioner, which demonstrates compliance with all local laws including local zoning, fire codes and building codes;

4.8.5 Identifying and demonstrating legal control of the proposed site, through lease, purchase, or other means, for the marijuana business; and

4.8.6 A completed full inspection of the proposed site premise by the Commissioner and the Division.

4.9 Retention of applications

4.9.1 Upon notification that an applicant was not selected by the lottery, the applicant may request the Commissioner retain the application for subsequent application periods within 1 year.

4.9.2 The Commissioner may contact an applicant with a retained application for any additional information required for subsequent application periods.

4.9.3 Any application retained by the Commissioner that meets the requirements of a subsequent application period within the 1-year retention period shall be automatically entered into a subsequent application period if the applicant has properly updated the application.

4.9.4 The Commissioner may not enter a retained application into a subsequent application period if:

4.9.4.1 Any individual included in the application is in violation of ownership restrictions Title 4 of the Delaware Code or this regulation; or

4.9.4.2 Any individual associated with the application has been found to be in violation of Title 4 of the Delaware Code or this regulation.

4.10 Grounds for refusal of a license

4.10.1 The Commissioner shall consider the convictions listed in 4 **Del.C.** §1354 as grounds for refusal of a license.

4.10.2 The Commissioner may refuse to license an applicant if a substantial objection is presented pursuant to 4 **Del.C.** §1354.

4.10.3 An applicant must meet each of the following requirements, as applicable:

4.10.3.1 Except as otherwise provided in this Section, if the applicant is a business entity, every owner, officer, and director of the business entity who holds more than 10% of the outstanding issued shares must meet each of the requirements of this Section.

4.10.3.2 The applicant must be at least 21 years of age. If the applicant is a business entity, then every owner, officer, and director of the business entity must be at least 21 years of age.

4.10.3.3 The applicant must submit to a criminal history record check in accordance with the requirements in 4 **Del.C.** §1347 and this regulation.

4.10.3.4 The applicant must fully complete all forms required by the Commissioner and may not knowingly or recklessly make a false statement of material fact to the Commissioner. The Commissioner

may cancel a license pursuant to 4 **Del.C.** §1331 and this regulation if subsequent to the issuance of the license, the Commissioner determines the licensee knowingly or recklessly made a false statement of material fact to the Commissioner.

4.10.4 The Commissioner may refuse to license an applicant that in the Commissioner's discretion, based on any information collected in the criminal background check conducted pursuant to 4 **Del.C.** §1347, presents a risk to the health or public safety of Delaware citizens.

**29 DE Reg. 221 (09/01/25)**

## 5.0 License Renewals, Transfers and Change of Information

5.1 License renewal process

5.1.1 All licensees must apply for renewal on or before the first day of the third month preceding the biennial expiration date of a license as provided in 4 **Del.C.** §1353. In addition, the following requirements apply:

5.1.1.1 A retail marijuana store licensee seeking renewal must comply with 4 **Del.C.** §1332 and this regulation.

5.1.1.2 A marijuana testing facility licensee seeking renewal must comply with 4 **Del.C.** §1333 and this regulation.

5.1.1.3 A marijuana cultivation facility licensee seeking renewal must comply with 4 **Del.C.** §1334 and this regulation.

5.1.1.4 A marijuana product manufacturing facility licensee seeking renewal must comply with 4 **Del.C.** §1335 and this regulation.

5.1.1.5 A social equity licensee seeking renewal must comply with 4 **Del.C.** §1337 and this regulation.

5.1.1.6 A microbusiness licensee seeking renewal must comply with 4 **Del.C.** §1341 and this regulation.

5.1.2 A marijuana establishment seeking renewal must submit:

5.1.2.1 The renewal application in the form designated by the Commissioner;

5.1.2.2 A criminal background check in accordance with 4 **Del.C.** §1347, including:

5.1.2.2.1 Proof of fingerprinting and state and federal criminal history records checks.

5.1.2.2.2 For applicants that are business entities, fingerprinting and criminal history record checks are required for officer, director, employee, and owner with an interest of 10% or more.

5.1.2.2.3 Any additional information requested by the Commissioner to verify aspects of the license, including additional information and supporting documentation related to the ownership and control of the license as described in subsection 4.4.3 of this regulation; and

5.1.2.2.4 Payment of the renewal fee determined by the Commissioner.

5.1.3 The Commissioner or the Division may conduct a full inspection of the licensed premise before renewing a license. If a licensee fails the inspection or submits a deficient application for renewal, the licensee may submit a plan to correct the deficiencies with an amended renewal application.

5.1.4 The Commissioner may deny a license renewal if:

5.1.4.1 The plan to correct deficiencies identified in an inspection is insufficient.

5.1.4.2 The amended renewal application is incomplete or deficient.

5.1.4.3 Applicant ownership and operational control violates Title 4 of the Delaware Code or this regulation.

5.1.4.4 The licensee violates Title 4 of the Delaware Code or this regulation during the license period.

5.1.5 A licensee who fails to apply for license renewal or whose license was not renewed by the Commissioner must cease operations at all premises and may not sell or give away marijuana to any entity or individual.

5.1.6 A license may be reinstated upon payment of the reinstatement fee specified by the Commissioner and submission of a reinstatement application approved by the Commissioner.

5.1.7 A microbusiness licensee may not request a license tier increase.

5.1.8 The Commissioner will make a decision on an application for renewal of license as prescribed 4 **Del.C.** §1353.

5.2 Transfer of license

5.2.1 A transfer of a license must meet the requirements in 4 **Del.C.** §1366.

5.2.2 The Commissioner may deny transfer of an interest for any proposed transferee if:

5.2.2.1 The proposed transferee does not meet the requirements of Title 4 of the Delaware Code or this regulation.

5.2.2.2 The proposed transferee has been convicted of or pleaded nolo contendere to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

5.2.2.3 The payment of taxes due in any jurisdiction is in arrears;

5.2.2.4 The proposed transfer violates state, local or federal law; or

5.2.2.5 Other good cause exists to deny the proposed transfer.

5.2.3 Any individual or entity identified as having ownership or control of a license may not hold an ownership interest that exceeds the limitations set forth in subsection 4.1.2.

5.2.4 If the Commissioner approves a transfer of an ownership interest of a license and subsequently the Commissioner finds that a transfer violates state, local, or federal law or other binding contractual agreements, the Commissioner may:
5.2.4.1 Issue a fine against any parties involved in the transfer;
5.2.4.2 Declare the transfer void; or
5.2.4.3 Cancel the license.
5.3 Change in location of business premise
5.3.1 A marijuana establishment may not change the premises where the license is to be used without approval of the Commissioner.
5.3.2 A licensee may apply to change the premises where the license is to be used by submitting an application and applicable fee to the Commissioner on a form prescribed by the Commissioner.
5.4 All material changes to a license require the express approval of the Commissioner.
**29 DE Reg. 221 (09/01/25)**

**6.0 General Compliance**
6.1 Ownership requirements
6.1.1 A social equity license may not be transferred to a person who does not meet the criteria in 4 **Del.C.** §1336 until at least 3 years have passed since the social equity license was initially awarded.
6.1.2 A change ownership of a license must meet the requirements in 4 **Del.C.** §1372 and this regulation.
6.2 General facility requirements
6.2.1 Marijuana establishments must ensure that their premises comply with all applicable local laws, regulations, and zoning requirements.
6.2.2 Marijuana establishments that handle or otherwise conduct activities with food, food ingredients, or food products must comply with all applicable requirements in the State of Delaware Food Code.
6.2.3 Marijuana establishments must ensure that their premises complies with all applicable federal workplace safety laws and regulations in accordance with the General Duty Clause of the OSH Act (Public Law 91-956) and 29 C.F.R. provided by the Occupational Safety and Health Administration (OSHA), including:
6.2.3.1 The presence of functioning fire and smoke detection systems, and, where applicable, fire suppression systems;
6.2.3.2 The presence of functioning carbon monoxide detection systems;
6.2.3.3 The prominent display of emergency procedures, including evacuations and shelter-in-place procedures;
6.2.3.4 Personnel access to procedures for the safe handling and operation of any applicable equipment or tools; and
6.2.3.5 Any other applicable federal, state, or local laws and regulations pertaining to workplace safety.
6.2.4 Marijuana establishments must ensure compliance with all applicable rules, regulations, and standards contained in:
6.2.4.1 National Fire Protection Association (NFPA) standards;
6.2.4.2 International Building Code (IBC); and
6.2.4.3 International Fire Code (IFC).
6.3 General security requirements
6.3.1 Marijuana establishments must ensure that all usable marijuana plants, marijuana, and marijuana products are stored in a locked and secured area.
6.3.2 Marijuana establishments must implement appropriate security and safety measures to deter and prevent the unauthorized entrance into areas containing marijuana plants, marijuana, and marijuana products, and the theft or diversion of marijuana plants, marijuana, and marijuana products. Security and safety measures must include the following:
6.3.2.1 Access to the premises
6.3.2.1.1 Access from outside the premises must be closely monitored and limited to primary entry points.
6.3.2.1.2 Entry into any area where marijuana plants, marijuana, or marijuana products are held must be limited to authorized personnel.
6.3.2.1.3 Visitors, repair and maintenance workers must be supervised in restricted areas;
6.3.2.1.4 Commercial grade locks appropriate for facilities requiring high levels of physical security are required on all perimeter entry doors.
6.3.2.1.5 All external entrances to indoor facilities on the premises must be lockable.
6.3.2.1.6 All perimeter windows must be in good condition and lockable.
6.3.2.2 Alarm system
6.3.2.2.1 The alarm system must be fully operational at all premises.
6.3.2.2.2 The alarm system must immediately alert a licensed third-party security company of an unauthorized breach of security.

6.3.2.2.3 The alarm system must include an audible alarm capable of being disabled remotely by the security company.

6.3.2.2.4 The alarm system must immediately send an automatic or electronic notification to local or municipal public safety personnel in the event of a loss of electrical support backup system.

6.3.2.2.5 The alarm system must prevent tampering with computers or electronic records.

6.3.2.2.6 Marijuana establishments must conduct a maintenance inspection and test of the alarm system at intervals no more than 30 days from the previous inspection or test. A marijuana establishment must promptly make all necessary repairs to ensure the proper operation of the alarm system.

6.3.2.3 Lighting. Any perimeter entry point of a marijuana establishment must have lighting sufficient for observers to see, and cameras to record, any activity within 10 feet of the gate or entry to the premises.

6.3.2.4 Video surveillance

6.3.2.4.1 A sufficient number of cameras must be permanently affixed to allow the viewing, in its entirety, of any area where marijuana plants, marijuana, or marijuana products are cultivated, manufactured, stored, or prepared for transfer or sale, or where samples for testing are collected, prepared, and sealed.

6.3.2.4.2 Video surveillance must meet the following requirements:

6.3.2.4.2.1 Minimum camera resolution is 720p;

6.3.2.4.2.2 All cameras must record continuously 24 hours per day or be motion activated and at a minimum of 15 frames per second;

6.3.2.4.2.3 All recorded images must clearly and accurately display the time and date. Time is to be measured in accordance with the U.S. National Institute Standards and Technology standards;

6.3.2.4.2.4 An electronic hard drive or comparable electronic storage device used only for the storage of surveillance system video footage must be secured on the premises, be on a third-party server, or be secured in another manner to protect from tampering or criminal theft; and

6.3.2.4.2.5 Video footage must be digitally recorded and held for 90 days for routine footage or up to 36 months if video contains information of significance.

6.3.2.4.3 A marijuana establishment must provide the Commissioner with access to the video 24 hours a day, 7 days a week through a secure internet connection.

6.3.2.5 In the event of a failure of an alarm or video surveillance system due to loss of electrical support or mechanical malfunction that is expected to exceed an 8-hour period, marijuana establishments must:

6.3.2.5.1 Notify the Commissioner within 24 hours;

6.3.2.5.2 Provide alternative security measures approved by the Commissioner, or close the authorized physical addresses impacted by the failure or malfunction until the alarm or video surveillance systems have been restored to full operation;

6.3.2.5.3 Maintain documentation for a period of at least 24 months after the event. The documentation must include:

6.3.2.5.3.1 All maintenance inspections and tests conducted on the alarm or video surveillance system;

6.3.2.5.3.2 Any servicing, modification, or upgrade performed on the alarm or video surveillance system;

6.3.2.5.3.3 The date of the action;

6.3.2.5.3.4 A summary of any actions performed; and

6.3.2.5.3.5 The name, signature, and title of the individual who performed the actions.

6.3.2.6 Marijuana establishments must maintain documentation for any alarm activation or other event which requires response by public safety personnel, and any unauthorized breach of security.

6.3.3 Theft and diversion. If a marijuana establishment discovers evidence of theft or diversion, the marijuana establishment must report the theft or diversion to the Commissioner and law enforcement within 1 business day. Within 30 business days of discovering the discrepancy, the marijuana establishment must:

6.3.3.1 Complete an investigation;

6.3.3.2 Amend the marijuana establishment's standard operating procedures, if directed by the Commissioner; and

6.3.3.3 Send a report of the investigation to the Commissioner.

6.4 General conduct of marijuana establishments

6.4.1 Marijuana establishments must conduct monthly inventories in accordance with the following:

6.4.1.1 On the date business commences, the marijuana establishment must conduct an initial comprehensive inventory review of all marijuana plants, marijuana, and marijuana products at all premises;

6.4.1.2 Documentation of all inventory reviews shall include, at a minimum, the date of the inventory, a summary of the inventory findings and the name, signature, and title of the individual or individuals who conducted the inventory; and

6.4.1.3 If an inventory review identifies a discrepancy, the marijuana establishment must notify the Commissioner within 24 hours of discovery of the event.

6.4.2 Marijuana establishments must maintain a current and accurate copy of an operating manual that includes:

6.4.2.1 Procedures for the oversight of the marijuana establishment, including documentation of the reporting and management structure of the marijuana establishment;

6.4.2.2 Procedures for the safe handling of marijuana plants, marijuana, and marijuana products;

6.4.2.3 Procedures to ensure accurate record keeping, including protocols to ensure that quantities of marijuana and marijuana products purchased do not suggest re-distribution;

6.4.2.4 Personnel security policies;

6.4.2.5 Safety and security procedures, including requirements in accordance with subsection 6.3 of this regulation, and including a disaster plan with procedures to be followed in case of fire or other emergencies;

6.4.2.6 Personal safety and crime prevention techniques;

6.4.2.7 Job descriptions or employment contracts developed for all employees and volunteer agreements for all volunteers which includes duties, responsibilities, authority, qualifications, and supervision;

6.4.2.8 The marijuana establishment's alcohol and drug free workplace policies;

6.4.2.9 Procedures to prevent theft or diversion;

6.4.2.10 A business continuity plan; and

6.4.2.11 Any additional operating manual requirements for the marijuana establishment's respective license type.

6.4.3 Personnel training. Marijuana establishments must develop, implement, and maintain on the premises an on-site training curriculum, or enter into contractual arrangements with outside resources capable of meeting personnel training requirements. All personnel must receive training in the following prior to commencing work on behalf of the marijuana establishment:

6.4.3.1 Proper use of security measures and controls that have been adopted by the marijuana establishment; and

6.4.3.2 Specific procedures for responding to an emergency, including accident, robbery, active shooter, or violent incident.

6.4.4 Employment identification badge

6.4.4.1 All personnel must have an employment identification badge issued by the Commissioner that permits the individual to conduct activities on behalf of the marijuana establishment. Employment identification badges must be visible on the individual's person at all times the individual is conducting activities on behalf of the marijuana establishment.

6.4.4.2 Applications for an employment identification badge must be submitted on forms made available by the Commissioner. Every applicant must be fingerprinted and complete a criminal history background check.

6.4.4.3 The Commissioner may deny an employment identification badge to any individual who:

6.4.4.3.1 Has been convicted of an offense listed in 4 **Del.C.** §1354(b)(4);

6.4.4.3.2 Does not provide sufficient documentation that the individual is 21 years of age or older; or

6.4.4.3.3 In the Commissioner's discretion, based on information collected in the criminal background check process, presents a risk to the health or public safety of Delaware citizens.

6.4.4.4 Employment identification badges must be renewed every 2 years in accordance with the following:

6.4.4.4.1 An application for renewal of an employment identification badge must be submitted prior to the expiration date, and no earlier than 60 days before the expiration date.

6.4.4.4.2 If an application for renewal of an employment identification badge has been submitted before the expiration date, but has not been processed by the Commissioner, personnel may conduct activities on behalf of the marijuana establishment until the new employment identification badge has been issued.

6.4.4.5 Employment identification badges for which a renewal application has not been received by the Commissioner will expire. Personnel with an expired badge may not conduct any activities on behalf of the marijuana establishment.

6.4.4.6 If an employment identification badge is lost or stolen, the marijuana establishment must notify the Commissioner within 24 hours. After notification, the Commissioner will indicate whether the badge holder may continue to conduct activities on behalf of the marijuana establishment.

6.4.4.7 Marijuana establishments must notify the Commissioner within 48 hours of the termination of the personnel's affiliation with the marijuana establishment. The marijuana establishment must follow instructions from the Commissioner for return of the employment identification badge.

6.4.4.8 The Commissioner may charge a fee for the issuance or replacement of an employment identification badge.

6.4.5 Marijuana establishments must conduct annual financial audits. The audit must be conducted by an independent auditing firm and submitted to the Commissioner with the marijuana establishment's annual report. The Commissioner or an auditing firm contracted by the Commissioner must have access to all books and records kept by any marijuana establishment at all times.

6.4.6 Prohibited conduct. Marijuana establishments may not:

6.4.6.1 Purchase marijuana plants, marijuana, or marijuana products from any person or entity other than another marijuana establishment licensed by the State of Delaware;

6.4.6.2 Sell or prepare products from a batch undergoing mandatory compliance testing until the marijuana testing facility has entered the applicable values into the seed-to-sale tracking system; or

6.4.6.3 Operate if an imminent health hazard exists due to an emergency such as fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent food-borne illness outbreak, gross unsanitary occurrences or conditions, or other circumstances that may endanger public health.

6.4.7 Visitor logs. Marijuana establishments must document and retain records following the entry of any individual not affiliated with the marijuana establishment into any area of the premises that is not accessible to the public.

6.4.7.1 Visitor logs must include the full legal name and signature of the visitor, the visitor's phone number, the date of the visitation, and a check-in and check-out time.

6.4.7.2 If the visitor is a holder of an active employment identification badge under this regulation, the visitor log must include the individual's unique identification number.

6.4.7.3 Visitor logs must be maintained for a period of 1 year following the date of visitation.

6.5 Retail marijuana store general requirements

6.5.1 A retail marijuana store license permits the following activities:

6.5.1.1 Purchasing prepackaged retail units of marijuana from marijuana cultivation facilities;

6.5.1.2 Purchasing prepackaged retail units of marijuana, marijuana concentrates, and marijuana products from marijuana products manufacturing facilities;

6.5.1.3 Selling prepackaged retail units of marijuana, marijuana concentrates, and marijuana products, to consumer 21 years or older or with a valid medical marijuana program card;

6.5.1.4 Providing samples of marijuana and marijuana products to authorized individuals for mandatory compliance testing in accordance with subsection 11.2 at the direction of the Commissioner;

6.5.1.5 Collecting samples of marijuana for research and development testing in accordance with subsection 11.7 and transporting those samples to a marijuana testing facility;

6.5.1.6 Storing prepackaged retail units of marijuana, marijuana concentrates, and marijuana products;

6.5.1.7 Selling marijuana accessories and non-consumable products that are not intended for human consumption, including clothing, storage containers, rolling papers, or other marijuana accessories.

6.5.1.8 Transporting prepackaged retail units of marijuana, marijuana concentrates, or marijuana products to other marijuana establishments; and

6.5.1.9 Destroying marijuana, marijuana concentrates and marijuana products in accordance with subsection 12.2.

6.5.2 A retail marijuana store is prohibited from:

6.5.2.1 Selling marijuana, marijuana concentrates, and marijuana products to a person under 21 years of age without a valid medical marijuana program card;

6.5.2.2 Selling more marijuana, marijuana concentrates, and marijuana products than is allowed for in 4 **Del.C.** §1332 and this regulation, during a single transaction to an individual;

6.5.2.3 Giving away marijuana, marijuana concentrates, and marijuana products for no remuneration;

6.5.2.4 Selling any marijuana, marijuana concentrates, and marijuana products which contain synthetic cannabinoids;

6.5.2.5 Selling marijuana, marijuana concentrates, and marijuana products to a person who is visibly intoxicated;

6.5.2.6 Displaying marijuana products in an insecure manner or in a manner that products can be viewed from outside the establishment;

6.5.2.7 Selling or giving away consumable products not containing marijuana, including cigarettes or alcohol, or any edible product that does not contain marijuana, including sodas, candies, or baked goods;

6.5.2.8 Selling retail marijuana or retail marijuana products over the Internet. This does not preclude online pre-orders for pick-up at the retail location, provided that the sale is not completed until all other requirements have been met, including identity and age verification; and

6.5.2.9 Delivering retail marijuana or retail marijuana products to a person not physically present in the retail marijuana store's licensed premises. Individuals holding a valid medical marijuana program card may receive home delivery.

6.5.3 A retail marijuana store must:

6.5.3.1 Ensure all sales of marijuana and marijuana products take place within the retail area of the retail marijuana store premises;

6.5.3.2 Prohibit the consumption of marijuana or marijuana products on the premises of the retail marijuana store;

6.5.3.3 Comply with all provisions of Delaware and federal law in regard to individuals with disabilities;

6.5.3.4 Prominently display the active retail marijuana store license where it can reasonably be viewed by state and local agencies and the public;

6.5.3.5 In addition to the training requirements described in subsection 6.4.3 of this regulation, ensure all employees are trained in recognizing valid identification cards; and

6.5.3.6 Verify customer age by reviewing the purchaser's government-issued photo identification card showing that the individual is 21 years of age or older or holds a valid medical marijuana program card. A valid, government-issued identification must contain a photo and the date of birth of the individual and be unexpired. Valid forms of government-issued identification include:

6.5.3.6.1 A driver's license issued by any state within the United States, District of Columbia, or U.S. territory;

6.5.3.6.2 An identification card, including a temporary identification card, issued by any state within the United States, District of Columbia, or U.S. territory;

6.5.3.6.3 A United States military identification card or any other identification card issued by the United States government including a permanent resident card, alien registration card, or consular card;

6.5.3.6.4 A passport or passport identification card; or

6.5.3.6.5 A tribal enrollment card issued by the governing authority of a federally recognized Indian tribe.

6.5.4 Retail marijuana store operating plan. Retail marijuana stores must maintain a current and accurate copy of an operating plan that includes:

6.5.4.1 Procedures for recognizing valid identification cards, including the duties and responsibilities of employees when presented with fraudulent identification by an individual under the age of 21;

6.5.4.2 Procedures for the safe handling of marijuana and marijuana products available for sale;

6.5.4.3 Requirements for the record keeping and disposal of marijuana and marijuana products removed from their original packaging for the purposes of displaying products available for sale; and

6.5.4.4 Procedures for the monthly inventory review of all marijuana and marijuana products for sale in accordance with subsection 7.1.2 of this regulation.

6.5.5 Display of marijuana and marijuana products. Marijuana and marijuana products available for sale at a retail marijuana store must be displayed:

6.5.5.1 In a manner that is not visible to the general public from a public right-of-way;

6.5.5.2 In a locked display case or container that can only be accessed with the assistance of an employee of the retail marijuana store.

6.5.5.2.1 A display case containing marijuana or marijuana products must include the potency of the marijuana or marijuana products next to the name of the marijuana or marijuana products using the standards established by Section 9.0 of this regulation.

6.5.5.2.2 If an individual wishes to inspect marijuana or a marijuana product located in a display case, an employee of the retail marijuana store must assist the individual and remain with them at all times while the product is being inspected.

6.5.5.2.3 Marijuana and marijuana products may be removed from their packaging and placed in a display case or container but may not be sold or consumed when the marijuana or marijuana product is no longer being used for display purposes.

6.5.6 A retail marijuana store may petition the Commissioner to allow deli style dispensing of marijuana flower. The Commissioner will consider the petition weighed against the health and public safety of consumers. The petition must demonstrate compliance with Section 9.0 of this regulation and include:

6.5.6.1 A detailed plan for selling unpackaged marijuana flower safely, without undue exposure to ubiquitous airborne contaminates;

6.5.6.2 A detailed plan for security and inventory control; and
6.5.6.3 A wholesale agreement with a licensed marijuana establishment providing marijuana flower.

6.5.7 Retail marijuana store security requirements

6.5.7.1 Retail area. A retail marijuana store must have a retail area where marijuana, marijuana products, or marijuana accessories are offered for sale. The retail area must:

6.5.7.1.1 Be physically separated from the waiting area; and

6.5.7.1.2 Be locked and accessible to customers only through permission by a retail marijuana store employee. A retail marijuana store employee may provide access by physically or remotely unlocking the entrance to the retail area for purposes of allowing a customer to enter the retail area.

6.5.7.2 Waiting area. A retail marijuana store must have a waiting area where marijuana, marijuana products, and marijuana accessories are not present. The waiting area must:

6.5.7.2.1 Be physically separated from the retail area;

6.5.7.2.2 Be the area first accessed by customers upon entrance into the premises;

6.5.7.2.3 Include a reception area where an employee of the retail marijuana store verifies that the purchaser has a valid government-issued photo identification card showing that the individual is 21 years of age or older; and

6.5.7.2.4 Be attended by a retail marijuana store employee at all times during operating hours.

6.6 Marijuana testing facilities general requirements

6.6.1 A marijuana testing facility license permits the following activities:

6.6.1.1 Receiving samples of marijuana and marijuana products from individuals authorized by the Commissioner for the purpose of required compliance testing;

6.6.1.2 Receiving samples of marijuana and marijuana products from marijuana cultivation facilities, marijuana product manufacturing facilities, retail marijuana stores, and individuals authorized by the Commissioner for the purpose of research and development;

6.6.1.3 Denying receipt of samples from to marijuana cultivation facilities, marijuana product manufacturing facilities, and retail marijuana stores, for any reason, including samples that do not meet the requirements of subsection 11.9;

6.6.1.4 Performing analysis of samples of marijuana and marijuana products following protocols approved by the Commissioner and in accordance with subsection 11.10;

6.6.1.5 Providing a Certificate of Analysis, for the sample provided to the marijuana testing facility, to marijuana cultivation facilities, marijuana product manufacturing facilities and retail marijuana stores;

6.6.1.6 Storing samples of marijuana and marijuana products;

6.6.1.7 Destroying and disposing of samples, subject to all requirements of subsection 12.2;

6.6.1.8 Reporting of testing results in accordance with subsections 11.5 and 11.10.9; and

6.6.1.9 Receiving samples of marijuana, marijuana concentrates, and marijuana products from individuals holding a valid medical marijuana program card or consumers 21 years or older, for the purpose of testing.

6.6.2 A marijuana testing facility must:

6.6.2.1 Operate in accordance with the International Organization for Standardization 17025 (ISO 17025) standards as confirmed by accreditation or by an International Laboratory Accreditation Corporation (ILAC) recognized accreditation body.

6.6.2.2 Meet the requirements specified in Sections 3.0 and 4.0 of this regulation.

6.6.3 Active licenses for marijuana testing facilities:

6.6.3.1 May not be issued prior to a final inspection and correction of any deficiencies in a manner acceptable to the Commissioner;

6.6.3.2 Must be kept posted in a conspicuous place on the premises;

6.6.3.3 Must clearly identify the name of the laboratory, the license number, the name of the marijuana testing facility director, the issue date, and expiration date; and

6.6.3.4 Must include a list of the analytes and methods for each test category for which the marijuana testing facility is approved to conduct testing. Test categories approved for the analysis of marijuana plant materials must be listed separately from those approved for marijuana concentrates.

6.6.4 Marijuana testing facilities may examine samples from other marijuana testing facilities in this state, provided that the marijuana testing facility providing the samples is licensed in this state pursuant to this regulation.

6.6.5 Marijuana testing facilities may receive samples from private citizens for examination. The individual or individuals providing samples will be responsible for any cost associated with examination and testing of the samples. Results obtained through examination of samples provided by private citizens are not subject to the reporting requirements in this regulation.

6.6.6 Management. Each marijuana testing facility must have a director who is responsible for the day-to-day management and operation of the marijuana testing facility, and for ensuring the achievement and maintenance of quality standards of practice.

6.6.6.1 The marijuana testing facility director must possess a doctorate degree in the chemical or biological sciences from a college or university accredited by a national or regional certifying authority and a minimum of 2 years of analytical laboratory experience or possess a master's degree in the chemical or biological sciences and a minimum of 4 years of analytical laboratory experience or possess a bachelor's degree in the chemical or biological sciences and a minimum of 5 years of analytical laboratory experience.

6.6.6.2 The marijuana testing facility director's responsibilities include:

6.6.6.2.1 Being present on the premises of the marijuana testing facility during the hours of operation to ensure adequate and appropriate supervision of marijuana testing facility activities;

6.6.6.2.2 Ensuring the accurate performance of all tests in the marijuana testing facility including the submission of appropriate reports on all tests;

6.6.6.2.3 Ensuring the supervision of all personnel in the marijuana testing facility and for hiring adequately trained personnel commensurate with the workload;

6.6.6.2.4 Being available during the hours of operation for personal or telephone consultation with personnel;

6.6.6.2.5 Notifying the Commissioner within 30 days of any change in marijuana testing facility services or supervisory personnel; and

6.6.6.2.6 Establishing and adhering to written policies and procedures for a comprehensive quality assurance program.

6.6.6.3 In the event the director of the marijuana testing facility is absent for a continuous period longer than 1 month in duration, the marijuana testing facility may not operate unless a person who meets the qualifications of subsection 6.6.6.1 of this regulation is in attendance.

6.6.6.4 The marijuana testing facility director must designate a qualified quality assurance management officer who is responsible for the marijuana testing facility's quality assurance management plan and its implementation. This individual may be an outside consultant or the marijuana testing facility director. The quality assurance management officer must:

6.6.6.4.1 Have a bachelor's degree in a chemical or biological science and 2 years of related laboratory experience. The Commissioner may waive these qualifications if the person has previous laboratory quality assurance experience acceptable to the Commissioner in a licensed, certified, or accredited laboratory, or possesses other qualifications acceptable to Commissioner;

6.6.6.4.2 Be responsible for the oversight of quality control data, including establishing acceptance criteria, documenting, and monitoring corrective action;

6.6.6.4.3 Where staffing allows, be independent of the technical areas for which they have quality assurance oversight;

6.6.6.4.4 Have general knowledge of the methodologies for which data review is performed;

6.6.6.4.5 Have oversight of the marijuana testing facility's quality assurance system; and

6.6.6.4.6 Conduct or arrange for annual internal audits of the technical operation of the marijuana testing facility, and report findings to the marijuana testing facility director.

6.6.7 Personnel. Each marijuana testing facility must:

6.6.7.1 Employ enough qualified personnel commensurate with the workload to ensure that services are provided effectively and safely and in accordance with prevailing laboratory standards and practices;

6.6.7.2 Establish a job description for each classification of position, clearly delineating qualifications, duties, and responsibilities inherent in each position;

6.6.7.3 Maintain personnel records for all personnel which include:

6.6.7.3.1 Current background and training documentation pertaining to qualifications;

6.6.7.3.2 Orientation procedures, including an initial demonstration of capability for each method or instrument the personnel will be performing or operating;

6.6.7.3.3 Evidence of periodic evaluation of work performance.

6.6.7.4 Train personnel initially and annually thereafter on the following:

6.6.7.4.1 Professional conduct, ethics, and state laws regarding marijuana;

6.6.7.4.2 The use of the seed-to-sale tracking system used by the marijuana testing facility; and

6.6.7.4.3 Testing methods employed by the marijuana testing facility.

6.6.8 Record keeping. In addition to the requirements and processes specified in Section 7.0 of this regulation, each marijuana testing facility must:

6.6.8.1 Create, control, and maintain records of raw data, chain-of-custody records, calculations, quality control data, and other essential documentation;

6.6.8.2 Complete all records with signatures, units of measurement, and documentation sufficient for verification of results; and

6.6.8.3 Retain all records in such a manner as to permit prompt retrieval and inspection by the Commissioner.

6.6.9 Quality assurance and quality control programs. Each marijuana testing facility must:

6.6.9.1 Have a quality assurance management plan that details the quality assurance system of quality control requirements in its standard operating procedures, and document that all personnel review the quality assurance management plan annually. The quality assurance/management plan must include:

6.6.9.1.1 Sample handling procedures;

6.6.9.1.2 Emergency sampling and handling plans;

6.6.9.1.3 Laboratory glassware, plastic ware, and equipment washing and sterilizing procedures;

6.6.9.1.4 Instrument calibration procedures;

6.6.9.1.5 A list of detailed analytical procedures or analytical references;

6.6.9.1.6 Data reduction, validation, and reporting procedures including non-compliance action plans;

6.6.9.1.7 Types and frequency of internal audit samples (quality control samples) and external audit samples (proficiency testing samples);

6.6.9.1.8 Internal audit procedures and frequencies;

6.6.9.1.9 Preventative maintenance procedures and schedules;

6.6.9.1.10 Procedures for determining accuracy and precision and method detection limits of all analytes and specified frequencies;

6.6.9.1.11 Control limits and corrective action policies;

6.6.9.1.12 Marijuana testing facility organization, staff, and responsibilities;

6.6.9.1.13 Procedures for marijuana testing facility and managerial data review;

6.6.9.1.14 Detection limits for cannabinoids and contaminant analytes specified in this regulation. Detection limits must be determined by detection limit studies prior to placing new methods in service and annually thereafter. The resulting detection limits must be less than half of the upper limit concentration criteria specified in this regulation. If the marijuana testing facility cannot meet a detection limit that is less than half of the upper limit for an analyte, a request for a variance must be submitted; and

6.6.9.1.15 The applicable quality control procedures required for methodologies described by the FDA, AOAC, AHP or USP.

6.6.9.2 Follow all applicable quality control activities described in its quality assurance/management plan as approved by the Commissioner;

6.6.9.3 Review their quality assurance management plan annually and provide a copy of the updated quality assurance/management plan to the Commissioner with the annual license renewal application;

6.6.9.4 Have clearly established internal and external quality controls to ensure high standards of performance and reliability of test results. These quality controls must consider factors including preventative maintenance, periodic inspection, testing for proper validation of methods, evaluation of reagents and volumetric equipment, surveillance of results, remedial action taken to correct deficiencies, and quality control failures and other factors as may be deemed necessary by the Commissioner;

6.6.9.5 Perform all analyses using methods that are currently approved by the Commissioner;

6.6.9.6 Make its quality assurance/management plan accessible to all personnel in the marijuana testing facility.

6.6.10 Proficiency testing and demonstration of capability. Each marijuana testing facility must adhere to the following:

6.6.10.1 The marijuana testing facility's quality assurance management plan must include standard procedures for determining the capability of its analysts before they can begin conducting quantitative analysis of marijuana or marijuana products.

6.6.10.2 The Commissioner must be notified when significant changes are made to the standard analytical procedures such as changes to extraction techniques, or the instrumentation used.

6.6.10.3 All personnel are required to perform initial demonstration of capability prior to implementing routine analyses.

6.6.10.4 Each marijuana testing facility must participate in a proficiency testing program approved by the Commissioner for each analyte (or group of analytes), matrix, and method for which the marijuana testing facility is allowed to conduct or for which it is requesting allowance. Proficiency testing samples must be procured from a proficiency testing provider approved by the Commissioner. The Commissioner may require that the proficiency testing program include

"round robin" proficiency testing whereby samples from the same batch are tested by more than 1 licensed marijuana testing facility for comparison of results.

6.6.10.4.1 If proficiency test samples are not commercially available, marijuana testing facilities must submit a plan to define and develop in-house quality control samples it will use to demonstrate its proficiency for each analyte, matrix, and method of analysis. The plan must include:

6.6.10.4.1.1 The source of the sample;

6.6.10.4.1.2 The matrix type;

6.6.10.4.1.3 Preparation procedures;

6.6.10.4.1.4 Target analytes in the sample;

6.6.10.4.1.5 How the analyte concentration was determined;

6.6.10.4.1.6 Control limits and how they were determined; and

6.6.10.4.1.7 Sample shelf life and expiration testing.

6.6.10.4.2 The laboratory must participate in a proficiency testing program annually for each analyte, matrix, and method and receive an acceptable evaluation for each test category described in this regulation.

6.6.10.4.3 Proficiency test results must be submitted by the accredited provider directly to the Commissioner by October 31 of each year. Marijuana testing facilities must designate the Commissioner as a recipient of the provider's proficiency test results report. Marijuana testing facilities may not communicate or receive proficiency test results to or from other marijuana testing facilities before the accredited provider makes them available.

6.6.10.4.4 When a marijuana testing facility receives an unacceptable evaluation for an analyte in a study, it must determine the cause for the failure, take corrective action, and participate in another proficiency testing study for the failed analyte. Documentation of the investigation and corrective must be maintained, and a copy provided to the Commissioner before the next proficiency testing study.

6.6.10.4.5 Failure to complete proficiency testing studies annually, or failure to obtain an acceptable result in a proficiency testing study will result in loss of approval for the testing of the analyte in question until 2 consecutive proficiency testing studies resulting in acceptable evaluations have been completed. There must be an interval of at least 30 days between the 2 studies.

6.6.10.4.6 All proficiency test samples must be analyzed in the same manner and frequency as real marijuana and marijuana products using the same staff, procedures, and equipment.

6.6.10.4.7 Marijuana testing facilities may not send a proficiency testing sample, or a portion thereof, to another marijuana testing facility for any analysis for which it is approved or seeking approval.

6.6.10.4.8 A marijuana testing facility may not knowingly receive any proficiency testing sample, or a portion thereof, from another marijuana testing facility for any analysis for which the sending marijuana testing facility is approved or seeking approval.

6.6.10.4.9 Marijuana testing facility management or personnel may not communicate with any individual at another marijuana testing facility concerning a proficiency testing sample or attempt to obtain the assigned value from their proficiency testing provider.

6.6.10.4.10 All raw data obtained in analyzing proficiency testing samples must be retained and be available for review for a minimum of 5 years.

6.6.11 Procedures manual. Each marijuana testing facility must have available at all times, in the immediate working areas of personnel engaged in conducting analytical laboratory sample receiving, sample accessioning, and testing, a procedures manual which includes a detailed compilation of all automated and manual methods and procedures for chain-of-custody, and analytical testing which is performed by the laboratory and for which it is approved. Procedures manuals must:

6.6.11.1 Be written in a uniformly consistent format;

6.6.11.2 Specify the approved method used;

6.6.11.3 Describe the quality control activities pertinent to the method;

6.6.11.4 Contain information concerning preparation and storage of media, reagents, control and calibration procedures, and pertinent literature references;

6.6.11.5 Describe the marijuana testing facility's technical procedures for the receiving, processing, and examination of samples;

6.6.11.6 For tests which are normally performed on automated test equipment, provide for alternate methods or for storage of test samples, in the event the automated equipment becomes inoperable; and

6.6.11.7 Be approved, signed, and dated by the current marijuana testing facility director and the quality assurance/management officer. Changes in procedures must be approved, signed, and dated by the current marijuana testing facility director and the quality assurance/management officer.

6.6.12 Waste disposal. In addition to the requirements and processes specified in Section 12.0 of this regulation, each marijuana testing facility must:

6.6.12.1 Manage medical waste per Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Delaware (7 **DE Admin. Code** 1302, Part 262 Standards Applicable to Generators of Hazardous Waste); and

6.6.12.2 Manage hazardous waste per DNREC rules and regulations.

6.6.13 Prohibited conduct. Marijuana testing facilities must adhere to the following requirements:

6.6.13.1 No marijuana testing facility or owner, officer, director, manager, general partner, or employee of a marijuana testing facility may have a direct or indirect financial interest in a marijuana cultivation facility, marijuana product manufacturing facility, or retail marijuana store.

6.6.13.2 A marijuana testing facility may not transfer any marijuana, marijuana products, or samples to any person or entity other than the person or entity who provided the sample, a law enforcement officer authorized to collect the marijuana or marijuana product, or another licensed marijuana testing facility with a valid license to perform the testing requested, or the Commissioner.

6.6.13.3 No owner, officer, director, manager, general partner, contractor, or employee of a marijuana testing facility may accept any gifts of goods, services, or money from a marijuana cultivation facility, marijuana product manufacturing facility, retail marijuana store, or a person or an organization representing the entities.

6.6.13.4 A marijuana testing facility must maintain the confidentiality of test results and may not report test results with any identifying information to anyone other than the person or entity who submitted the sample, law enforcement officers authorized to collect the information, the CDC, or the Commissioner.

6.6.13.5 No employee of a marijuana testing facility may alter the results of any test. In cases in which a sample was retested in accordance with Section 11.0 of this regulation, both test results must be maintained.

6.6.13.6 No employee of a marijuana testing facility may conceal from the Commissioner the results of any mandatory test for cannabinoid content or contamination.

6.6.13.7 A marijuana testing facility must maintain its accreditation at all times for at least 1 analyte and technology required as part of mandatory compliance testing to remain licensed by the Commissioner.

6.6.14 Marijuana testing facilities security requirements

6.6.14.1 Facility requirements. Each marijuana testing facility must adhere to the following:

6.6.14.1.1 Be housed in well-lighted, sanitary, vented quarters equipped with hot and cold running water and bathroom facilities, and contain ample space to process and examine the samples commensurate with the total workload;

6.6.14.1.2 Be in distinct and separate locations from living quarters unless provisions exist for separate entrances, and plumbing fixtures;

6.6.14.1.3 Have ample workbench space, have sufficient water, gas, suction, electrical outlets, and sinks;

6.6.14.1.4 Have adequate and proper storage space for all chemicals including explosive, flammable, corrosive, and caustic materials;

6.6.14.1.5 Have flooring composed of non-porous material in laboratory areas where acids, caustics, and solvents are used;

6.6.14.1.6 Have adequate temperature and humidity controls as may be required for proper performance of tests and operation of instruments affected by environmental conditions;

6.6.14.1.7 Have adequate electrical supply; and

6.6.14.1.8 Have adequate refrigeration for samples, standards, and reagents used in testing.

6.6.14.2 Equipment and supplies. Each marijuana testing facility must adhere to the following:

6.6.14.2.1 Possess on-site all equipment necessary for the testing method.

6.6.14.2.2 Have sufficient glassware and plastic lab-ware necessary for the analyses. Glassware shall be borosilicate glass or other corrosion-resistant glass and free of cracks and chips.

6.6.14.2.3 Markings and etchings shall be legible. Volumetric flasks, pipettes, and other glassware used for volumetric analysis shall be class "A".

6.6.14.2.4 The marijuana testing facility must have sufficient facilities to wash and sterilize glassware, lab-ware, and other containers used in the analyses.

6.6.14.2.5 All precision equipment and instruments (e.g., pipettes, pH meters, conductivity meters) must be calibrated and checked for accuracy at regular intervals as required by the method and the marijuana testing facility's quality assurance policies. Documentation of calibration and accuracy checks must be maintained. Records of service by a qualified instrument service organization shall be maintained.

6.6.14.2.6 Analytical balance range and sensitivity must be appropriate for the application for which it is used. Balances must be kept clean and free of corrosion and spillage and shall be checked daily with weights meeting ASTM Type I, Class 1 or 2 specifications with values that bracket the laboratory's weighing needs. Records must be maintained that include acceptance criteria for the checks. ASTM weights shall be recalibrated every 5 years or immediately if nicked or corroded. Non-reference weights may be used but must be calibrated every 6 months against ASTM type 1, 2 or 3 weights.

6.6.14.2.7 All balances must be calibrated annually by a professional balance service. Certificates of calibration must be maintained at the marijuana testing facility.

6.6.14.2.8 All incubators, refrigerators, ovens, autoclave or sterilizers, and water baths must contain calibrated thermometers. The marijuana testing facility must maintain copies of the certificates of calibration for each thermometer. Thermometer range and graduation increments must be appropriate for the application for which it is used. Glass thermometers must be checked for accuracy annually, and other types of thermometers quarterly, by comparing with a NIST traceable thermometer at the temperatures of interest. Thermometers must be tagged with the initials of person who conducted the check, the date of accuracy check, and the correction factor (may be 0). There may be no separation in the liquid column of glass thermometers. Calibrated thermometers may be substituted for automated temperature recording systems. If this substitution is made, the marijuana testing facility must maintain copies of the certificates of calibration for the equipment. The automated temperature recording system must be checked for accuracy annually.

6.6.14.2.9 Use analytical reagent grade chemicals unless otherwise allowed or specified by the analytical method.

6.6.14.2.10 Date bottles of dehydrated microbiology media when received and opened. Marijuana testing facilities may not use media beyond the manufacturer's expiration date or beyond 1 year from opening, whichever is sooner. Media must be discarded immediately if caked or otherwise deteriorated. Prepared or prepackaged media are permitted.

6.6.14.2.11 Use plastic lab-ware for microbiology that is clear and non-toxic.

6.6.14.2.12 Reagent water for chemical analyses and for general use must be distilled or deionized and have a resistivity value greater than 0.5 megaohms/cm or a conductivity value of less than 2 microhmos/cm at 25° C. Quality checks shall be made according to specified analytical method requirements, but at least monthly, with a conductivity meter. All quality checks must be recorded.

6.6.14.2.13 For microbiological analyses, reagent water must meet all the following criteria:

| PARAMETER | LIMITS | FREQUENCY |
|---|---|---|
| Resistivity | >0.5 megaohms/cm | Monthly |
| Pb, Cd, Cr, Cu, Ni, Zn | <0.05 mg/L per contaminant, and <0.1 mg/L total | Annually |
| Total chlorine residual | Non-detectable | Monthly |
| Heterotrophic plate count | <500 CFU/mL | Monthly |

| | | |
|---|---|---|
| Bacteriological quality of reagent water | Ratio of growth rate: 0.8 to 3.0<br><br>(See Standard Methods, Section 9020B. This test is not required if marijuana testing facilities use water that meets the criteria for Types I and II water as defined in Standard Methods Section 1080). | Annually |

6.6.14.2.14 Label all reagents and solutions to indicate identity, concentration, storage requirements, expiration dates and any other pertinent information.

6.6.14.2.15 Date all reagents and solutions when received and opened. Marijuana testing facilities may not use materials beyond their expiration dates.

6.6.14.2.16 All marijuana testing facility prepared reagents and solutions must be labeled with preparation and expiration dates. No laboratory prepared materials may be used beyond their expiration dates.

6.6.14.3 Safety and security. Marijuana testing facilities must:

6.6.14.3.1 Include safety instructions in a laboratory safety manual for the protection of personnel from physical, chemical, and biological hazards. The laboratory safety manual must include applicable programs for the protection of employees as outlined in the Code of Federal Regulations (29 C.F.R. Part 1910), including the Occupational Safety and Health Administration standards for hazard communication, and occupational exposure to hazardous chemicals in laboratories;

6.6.14.3.2 Keep samples, standards, reagents, solvents, acids, chemicals, and data in restricted access areas;

6.6.14.3.3 Implement the general security requirements required in subsection 6.3 of this regulation.

6.7 Marijuana cultivation facility general requirements

6.7.1 Marijuana cultivation facilities are permitted to:

6.7.1.1 Plant and cultivate marijuana plants, subject to the limits associated with each tier of license;

6.7.1.2 Harvest, trim, dry, and cure marijuana plants;

6.7.1.3 Store harvested marijuana, including kief and marijuana trim;

6.7.1.4 Sell and distribute marijuana, including kief and marijuana trim to marijuana cultivation facilities, marijuana product manufacturing facilities, and retail marijuana stores;

6.7.1.5 Provide samples of marijuana and marijuana products to the Division for mandatory compliance testing in accordance with Section 11.0 of this regulation at the direction of the Commissioner;

6.7.1.6 Collect samples of marijuana and marijuana products for research and development testing and transport those samples to a marijuana testing facility;

6.7.1.7 Prepare, package, and label marijuana into individual retail units for wholesale to a retail marijuana store;

6.7.1.8 Transport marijuana to marijuana products manufacturing facilities and retail marijuana stores; and

6.7.1.9 Destroy marijuana plants and marijuana in accordance with Section 12.0 of this regulation.

6.7.2 Marijuana cultivation facilities may not:

6.7.2.1 Produce marijuana concentrates, tinctures, extracts, or other marijuana products;

6.7.2.2 Sell marijuana or marijuana products directly to consumers; and

6.7.2.3 Permit marijuana or marijuana products to be consumed on the premises of the marijuana cultivation facility.

6.7.3 Standard operating procedures. A marijuana cultivation facility must establish standard operating procedures in accordance with subsection 6.4.2 of this regulation for all aspects of the planting, cultivating, harvesting, trimming, drying, curing, storing, selling, distributing, sampling, preparing, packaging, labeling, transporting, tracking, and destroying of marijuana plants. The standard operating procedures must include:

6.7.3.1 The creation and timely entry of accurate data into an inventory control system that identifies and tracks the marijuana cultivation facility's inventory of marijuana from the seed or immature plant to the time they are sold or transferred to another marijuana establishment;

6.7.3.2 The safe and sanitary storage of marijuana and marijuana products, including maintaining the cleanliness of any building or equipment used to store or display marijuana or marijuana products;

6.7.3.3 The procedure for providing a sample of its marijuana to the Division for testing and research purposes as required by Section 11.0 of this regulation;

6.7.3.4 The creation and maintenance of a record of samples provided to the Division for the purposes of mandatory compliance testing, the identity of the marijuana testing facility that tested the samples, and the results of the mandatory compliance testing;

6.7.3.5 The proper packaging and labeling of marijuana to be sold to retail marijuana stores, as required by Section 9.0 of this regulation;

6.7.3.6 The selling or transferring of marijuana, including seeds, immature plants, mature plants, and packaged and labeled marijuana, to retail marijuana stores, marijuana product manufacturing facilities, and other marijuana cultivation facilities;

6.7.3.7 The proper disposal and segregated storage of marijuana that is outdated, damaged, deteriorated, misbranded, or adulterated;

6.7.3.8 The training of all personnel in the standard operating procedures and retention of attendance records; and

6.7.3.9 A copy of the standard operating procedures must be readily available on-site for inspection by the Commissioner.

6.7.4 A marijuana cultivation facility must have an environmental and sustainability plan that includes efforts the facility will take to minimize the environmental impact of its operations and plans to minimize water usage.

6.7.5 Batch size. Marijuana cultivation facilities may not package marijuana in batches larger than 10 pounds.

6.7.6 Marijuana cultivation facility security requirements

6.7.6.1 Marijuana cultivation facilities must comply with the following facility protocols:

6.7.6.1.1 Ensure all activities related to the cultivation of marijuana plants take place within a fully enclosed secure indoor facility or within a secured fenced area;

6.7.6.1.2 Have sufficient gas, suction, electrical outlets, sinks, hot and cold running water, and bathroom facilities;

6.7.6.1.3 Have adequate temperature and humidity controls;

6.7.6.1.4 Prominently display a list of all trained personnel inside or immediately outside of the extraction area; and

6.7.6.1.5 Process only marijuana that has been harvested in areas designated for processing.

6.7.6.2 Marijuana cultivation facilities must comply with the following safety and security protocols:

6.7.6.2.1 Update their safety, security, and prevention and diversion plan upon requesting a 1-tier increase in size each renewal period; and

6.7.6.2.2 Implement the general security requirements required in subsection 6.3 of this regulation.

6.8 Marijuana product manufacturing facility general requirements

6.8.1 Standard operating procedures. A marijuana product manufacturing facility must establish standard operating procedures in accordance with subsection 6.4.2 of this regulation for all aspects of the receipt, processing, storage, packaging, labeling, handling, tracking, and shipping of products containing marijuana and marijuana waste. The standard operating procedures must be readily available for on-site inspection by the Commissioner and include:

6.8.1.1 The creation and timely entry of accurate data into an inventory control system that identifies and tracks the marijuana product manufacturing facility's stock of marijuana and marijuana products from the time they are delivered or produced to the time they are delivered to another marijuana establishment;

6.8.1.2 The creation and maintenance of a record of samples provided to a licensed marijuana testing facility, the identity of the marijuana testing facility, and the results of the mandatory compliance testing;

6.8.1.3 The sanitary storage of marijuana and marijuana products, including maintaining the cleanliness of any building or equipment used to store or display marijuana or marijuana products; and

6.8.1.4 The training of all personnel in the standard operating procedures and retention of attendance records.

6.8.2 A marijuana product manufacturing facility must have a standard operating procedure to:

6.8.2.1 Maintain the marijuana and marijuana products free from contamination;

6.8.2.2 Meet the sanitary standards for food preparation as described in 4 **Del.C.** §1335(f).

6.8.2.3 Report any personal health condition that might compromise the cleanliness or quality of the marijuana or marijuana products.

6.8.3 A marijuana product manufacturing facility's standard operating procedure must provide for disposal and segregated storage of any marijuana or marijuana product:

6.8.3.1 That is outdated, damaged, deteriorated, misbranded, or adulterated; or

6.8.3.2 Whose containers or packages have been improperly or accidentally opened.

6.8.4 Equipment sanitation, accuracy, and maintenance logs. A marijuana product manufacturing facility's standard operating procedure must provide for maintaining the sanitation of equipment that comes in

contact with marijuana or marijuana products. The marijuana product manufacturing facility must ensure that:

6.8.4.1 Automatic, mechanical, or electronic equipment is routinely calibrated and periodically checked to ensure proper performance; and

6.8.4.2 Any scale, balance, or other measurement device is routinely calibrated and periodically checked to ensure accuracy.

6.8.5 The marijuana product manufacturing facility must maintain an accurate log recording the cleaning and calibration of equipment. Weighing or measuring devices must be certified and calibrated in accordance with applicable requirements of the Delaware Department of Agriculture.

6.8.6 A marijuana product manufacturing facility may acquire hemp from a person licensed to produce hemp by the Delaware Department of Agriculture or the Secretary of the U.S. Department of Agriculture. Any product derived from hemp must comply with the testing requirements established in Section 11.0 of this regulation prior to distribution to a retail marijuana store.

6.8.7 A marijuana product manufacturing facility may not:

6.8.7.1 Add any marijuana to a food product where the manufacturer of the food product holds a trademark to the food product's name; except that a manufacturer may use a trademarked food product if the manufacturer uses the product as a component or as part of a recipe and where the marijuana product manufacturer does not state or advertise to the consumer that the final retail marijuana product contains a trademarked food product;

6.8.7.2 Intentionally or knowingly label or package a retail marijuana product in a manner that would cause a reasonable consumer confusion as to whether the retail marijuana product was a trademarked food product; or

6.8.7.3 Label or package a product in a manner that violates any federal trademark law or regulation.

6.8.8 Retail marijuana products must be prepared in a marijuana product manufacturing facility that is used exclusively for the manufacture and preparation of retail marijuana or retail marijuana products and using equipment that is used exclusively for the manufacture and preparation of retail marijuana products. Marijuana establishments must obtain approval of the Commissioner to co-locate multiple marijuana establishment license types on a single premises. The Commissioner may approve such application if the following conditions are met:

6.8.8.1 The co-located facilities are clearly delineated from each other in all plans;

6.8.8.2 Any shared space complies with all regulations applicable to each of the co-located license types;

6.8.8.3 The co-located facilities are physically separated by a permanent physical barrier or wall; and

6.8.8.4 The co-located facilities are connected by a single, lockable door.

6.8.9 Marijuana or marijuana products may not be consumed on the premises of a marijuana product manufacturing facility.

6.8.10 Permissible extractions. Except as provided in subsection 6.8.11 of this regulation, marijuana extraction shall only be conducted using the following methods:

6.8.10.1 Mechanical extraction, such as dry screens, sieves, or presses, potable water and ice made from potable water, cryogenic or subzero manufacturing not involving a solvent, or pressure and temperature.

6.8.10.2 Chemical extraction using a nonvolatile solvent such as a non-hydrocarbon-based or other solvent such as water, vegetable glycerin, vegetable oils, animal fats, or food-grade glycerin, (non-hydrocarbon-based solvents shall be food grade).

6.8.10.3 Chemical extraction using a division approved closed loop extraction system.

6.8.11 To request authorization from the Commissioner to conduct marijuana extraction using a method other than those specified in subsection 6.8.10 of this regulation, the marijuana establishment must submit a detailed description of the extraction method, including any documentation that validates the method and any safety procedures to be utilized to mitigate any risk to public or worker health and safety.

6.8.12 Extraction equipment shall be used and operated in accordance with its intended manufacturer use and design.

6.8.13 Current safety data sheets shall be kept on the premises for all chemicals used in the extraction process.

6.8.14 Any form of alkane or petroleum hydrocarbon extraction is unauthorized in Delaware.

6.8.15 Volatile solvent extractions. Chemical extractions using volatile solvents are subject to the following minimum requirements:

6.8.15.1 Hydrocarbon-based solvents must be at least 99.5% purity with a Certificate of Analysis from the manufacturer to confirm purity.

6.8.15.2 Ethyl alcohol must be food grade, and non-denatured in composition.

6.8.15.3 Solvents must be free of odorants, bitterants, or other additives and stored, handled, and disposed of in accordance with local, state, and federal regulations.

6.8.15.4 All extractions may be performed in a closed loop extraction system, unless approved by the Commissioner in accordance with subsection 6.8.11 of this regulation.

6.8.15.5 Marijuana product manufacturing facilities may not use ignition sources including heat guns or any open flame source next to extraction equipment that utilizes volatile solvents, including in rooms designated solely for extraction or in areas that contain or uses flammable liquids and gasses.

6.8.16 Closed-loop extraction system requirements. Closed loop systems, other equipment used, the extraction operation, and facilities must be approved for use by the local fire code official and meet any required fire, safety, and building code requirements specified in:

6.8.16.1 National Fire Protection Association (NFPA) standards;

6.8.16.2 International Building Code (IBC);

6.8.16.3 International Fire Code (IFC); and

6.8.16.4 Other applicable standards including all applicable fire, safety, and building codes related to the processing, handling and storage of the applicable solvent or gas.

6.8.17 The Commissioner must be notified when significant changes are made to the standard analytical procedure such as changes to extraction technique, or the instrumentation used.

6.8.18 Marijuana product manufacturing facility security requirements

6.8.18.1 Facility requirements. Each marijuana product manufacturing facility must adhere to the following:

6.8.18.1.1 Be housed in well-lighted, sanitary, vented quarters equipped with hot and cold running water and bathroom facilities, and contain ample space to process and examine the samples commensurate with the total workload;

6.8.18.1.2 Be in distinct and separate locations from living quarters unless provisions exist for separate entrances, and plumbing fixtures;

6.8.18.1.3 Have ample workbench space, have sufficient water, gas, suction, electrical outlets, and sinks;

6.8.18.1.4 Have adequate and proper storage space for all chemicals including explosive, flammable, corrosive, and caustic materials;

6.8.18.1.5 Have flooring composed of non-porous material in laboratory areas where acids, caustics, and solvents are used;

6.8.18.1.6 Have adequate temperature and humidity controls as may be required for proper operation of instruments affected by environmental conditions;

6.8.18.1.7 Prominently display a list of all trained personnel inside or immediately outside of the extraction area: and

6.8.18.1.8 Have adequate electrical supply.

6.8.18.2 Safety and security. Marijuana product manufacturing facilities must:

6.8.18.2.1 Establish and maintain adequate safety and security precautions;

6.8.18.2.2 Include safety instructions for the protection of personnel from physical, chemical, and biological hazards;

6.8.18.2.3 Provide each member of management and personnel a safety orientation and annually review policies and procedures in the safety manual including the proper use of security measures and procedures that have been adopted specific to responding to an emergency, including robbery, violence, or accident;

6.8.18.2.4 Keep samples, standards, reagents, solvents, acids, chemicals, and data in restricted access areas;

6.8.18.2.5 Supervise visitors, repair worker, and maintenance workers in restricted areas; and

6.8.18.2.6 Implement the minimum-security requirements required in subsection 6.3 of this regulation.

6.9 Marijuana micro-businesses are required to adhere the requirements in 4 **Del.C.** §§1340 and 1343 and this regulation.

## 7.0 Tracking, Transportation, and Record Keeping

7.1 General tracking requirements

7.1.1 Marijuana establishments must track all marijuana plants, marijuana, and marijuana products from seed to the point of sale, using the seed-to-sale tracking system specified by the Commissioner.

7.1.2 Marijuana establishments must record the following data in the seed-to-sale tracking system:

7.1.2.1 A complete inventory of all seeds, marijuana plants, immature marijuana plants, mother plants and flowering plants, marijuana, and marijuana products in the possession, control, or ownership of the marijuana establishment;

7.1.2.2 When cuttings are propagated, or seeds germinate;

7.1.2.3 Any changes to inventory of any marijuana plants, marijuana, and marijuana products;

7.1.2.4 When marijuana plants are partially or fully harvested or destroyed;

7.1.2.5 When marijuana waste is destroyed;

7.1.2.6 When an authorized transfer occurs;

7.1.2.7 Any unauthorized diversion, irregular movement, or discrepancies in inventory of marijuana plants, marijuana, or marijuana products;
7.1.2.8 All sales records;
7.1.2.9 All testing samples, including samples for research and development, and mandatory compliance test results;
7.1.2.10 The application of any substances for controlling pests, fungi, or other plant health issues; and
7.1.2.11 Any other information required by the seed-to-sale tracking system or specified by the Commissioner.

7.1.3 Any misstatements or omissions shall be a violation of this regulation.

7.1.4 Proper use of the inventory seed-to-sale tracking system does not relieve a marijuana establishment of its responsibility to maintain compliance with all laws, rules, and other requirements.

7.2 Implementation of the seed-to-sale tracking system

7.2.1 Marijuana establishments must have a seed-to-sale tracking system account activated and functional prior to operating or exercising any privileges of a license, unless excused by the Commissioner in writing.

7.2.2 Marijuana establishments may not enter any inventory into the seed-to-sale tracking system until the marijuana establishment receives an active license from the Commissioner.

7.2.3 Marijuana establishments must designate a current onsite employee as the seed-to-sale tracking system administrator. Marijuana establishments must notify the Commissioner when the seed-to-sale tracking system administrator changes and the qualifications of the replacement administrator.

7.2.4 Marijuana establishments must notify the Commissioner of any hiring, termination, or significant change in role of personnel authorized to use the seed-to-sale tracking system within 5 business days.

7.2.5 Marijuana establishments are responsible for all costs associated with the use of the seed-to-sale tracking system.

7.3 Requirements for use of the seed-to-sale tracking system

7.3.1 Marijuana establishments must reconcile all on-premises and in-transit marijuana plants, marijuana, and marijuana product inventories, and sales records, each day in the seed-to-sale tracking system by 11:59 p.m. that same day. If reconciliation is not possible due to external delays, notify the Commissioner the following business day and specify the situation causing the delay.

7.3.2 Marijuana establishments must utilize a standard of weights and measures that is supported by the seed-to-sale tracking system. Any scale used to weigh product prior to entry into the inventory seed-to-sale tracking system must be certified in accordance with Section 6.0 of this regulation.

7.3.3 Marijuana establishments must maintain the security of the seed-to-sale tracking system by adhering to the following:

7.3.3.1 Only employees of the marijuana establishment are authorized to access the seed-to-sale tracking system.
7.3.3.2 Employees must be trained before being given access to the seed-to-sale tracking system.
7.3.3.3 The marijuana establishment is accountable for all actions employees take while logged into the seed-to-sale tracking system.
7.3.3.4 Each individual user is accountable for their actions while logged into the seed-to-sale tracking system.
7.3.3.5 Each individual user shall only log activities in the seed-to-sale tracking system under the user's own unique seed-to-sale tracking system account.

7.3.4 The marijuana establishments using the seed-to-sale tracking system is responsible for the accuracy of all information entered into the seed-to-sale tracking system.

7.4 Requirements for use of third-party software

7.4.1 Marijuana establishments may use separate software applications to collect information to be used by the business, including secondary tracking or point of sale systems.

7.4.2 Marijuana establishments must ensure all relevant seed-to-sale tracking system data is accurately transferred to and from the seed-to-sale tracking system for the purposes of reconciliations with any secondary systems.

7.4.3 The seed-to-sale tracking system data is the primary source of inventory data, and any third-party software application must be compatible with the seed-to-sale tracking system.

7.4.4 Third party software for online product reservation shall integrate properly with inventory seed-to-sale tracking system.

7.5 Seed-to-sale tracking system procedures

7.5.1 A marijuana establishments' seed-to-sale tracking system must accurately accomplish the following:

7.5.1.1 Indicate the creation of a harvest batch or production batch including the assigned harvest batch or production batch number.
7.5.1.2 Identify when inventory is no longer on the premises or is part of a transfer to another marijuana establishment, including samples for mandatory compliance testing.

7.5.1.3 Indicate test results from a licensed testing facility, as applicable.
7.5.1.4 Record all remediation steps taken to remediate any batches of marijuana or marijuana products that fail testing.
7.5.1.5 Indicate the seed-to-sale tracking system item categories for all marijuana and marijuana products.
7.5.1.6 Record the actual wholesale price of all marijuana and marijuana products sold or transferred to another marijuana establishment.
7.5.1.7 Record the actual retail price of all marijuana and marijuana products sold to a consumer.

7.5.2 Each marijuana establishments must maintain a plan in the event the marijuana establishment loses access to the seed-to-sale tracking system. The plan must be available for inspection by the Commissioner or the Division at any time.

7.5.2.1 The plan for continuing operations during temporary seed-to-sale tracking system failures must be operational on the first day the marijuana establishment is open for business and include specific forms or procedures to be used. Marijuana establishments must immediately notify the Commissioner and must keep and maintain comprehensive records detailing all marijuana plants, marijuana, and marijuana product tracking activities that were conducted during the loss of access.

7.5.2.2 Once access is restored, all marijuana plants, marijuana, and marijuana product tracking activities that occurred during the loss of access must be entered into the seed-to-sale tracking system and the Commissioner shall be notified access has been restored. Records maintained during the tracking system outage must be retained for at least 2 years.

7.5.2.3 In the event of a statewide outage of the seed-to-sale tracking system that is expected to last more than 24 hours, the Commissioner shall notify marijuana establishments of any interim tracking procedures or requirements for the duration of the outage.

7.6 General transportation requirements

7.6.1 All marijuana plants, marijuana, and marijuana products, including samples for mandatory compliance testing and research and development, must be transported in accordance with the following requirements:

7.6.1.1 Transportation may only be conducted between marijuana establishments;
7.6.1.2 Transportation may only be conducted with a transport manifest generated by the seed-to-sale tracking system;
7.6.1.3 Transportation may only be conducted while the marijuana plants, marijuana, or marijuana products are contained within an enclosed, locked area in the transport vehicle;
7.6.1.4 Transportation method must maintain the integrity and safety of packaging and products; and
7.6.1.5 All marijuana plants, marijuana, and marijuana products must be shielded from public view.

7.6.2 All marijuana plants, marijuana, and marijuana products, including samples for compliance testing, being transported may not be removed from the vehicle until arrival at the destination or transferred or stored at any unlicensed premises.

7.6.3 Marijuana establishments transporting marijuana plants, marijuana, or marijuana products may not conduct any stops between registered facilities except:

7.6.3.1 To accommodate meals and rest periods required by law.
7.6.3.2 To refuel the transport vehicle.
7.6.3.3 Emergency stops, in which case the marijuana establishments transporting the marijuana plants, marijuana, or marijuana products must promptly notify the Commissioner of the reasons for the stop;
7.6.3.4 The marijuana establishments may make multiple deliveries to other licensed premises; and
7.6.3.5 During any stop while transporting product, personnel with a valid employee identification badge issued by the Commissioner must stay with the vehicle at all times.

7.6.4 Vehicles used for transporting marijuana plants, marijuana, and marijuana products must:

7.6.4.1 Be insured at or above the legal requirements in Delaware;
7.6.4.2 Be equipped with a functional alarm system;
7.6.4.3 Allow only personnel with valid employee identification badge issued by the Commissioner pursuant to subsection 6.4.4 in transport vehicles while transporting marijuana plants, marijuana, or marijuana products;
7.6.4.4 Be equipped with a GPS tracking device; and
7.6.4.5 If requested by the Commissioner, pass an inspection by the Commissioner or the Division before transporting marijuana plants, marijuana, and marijuana products.

7.6.5 Marijuana establishments receiving marijuana plants, marijuana, or marijuana products must:

7.6.5.1 Verify the condition and quantity of marijuana plants, marijuana, or marijuana products included in the transport manifest;

7.6.5.2 Record in the seed-to-sale tracking system and any other relevant business records any refused marijuana plants, marijuana, or marijuana products, or other discrepancies found between the marijuana plants, marijuana, or marijuana products delivered and the marijuana plants, marijuana, or marijuana products on the transport manifest;

7.6.5.3 Enter the received marijuana plants, marijuana, or marijuana products in the seed-to-sale tracking system in accordance with subsection 7.1.2 of this regulation; and

7.6.5.4 Provide an authorized signature of the personnel receiving the marijuana plants, marijuana, or marijuana products on the transport manifest belonging to the party transporting the marijuana plants, marijuana, or marijuana products.

7.6.6 Marijuana establishments transporting the marijuana plants, marijuana, or marijuana products must retain a copy of the transport manifest for their records.

7.6.7 Marijuana product manufacturing facility personnel receiving delivery must:

7.6.7.1 Log into the electronic manifest.

7.6.7.2 Take custody of a shipment of products containing marijuana.

7.6.7.3 Confirm that:

7.6.7.3.1 The transportation personnel is carrying appropriate identification.

7.6.7.3.2 The packaging is secure, undamaged, and appropriately labeled.

7.6.7.3.3 Each package in the shipment is labeled as described in the electronic manifest; and

7.6.7.3.4 The contents of the shipment are as described in the electronic manifest.

7.6.7.4 Record the confirmations in the electronic manifest.

7.6.7.5 Obtain in the electronic manifest the signature or identification number of the transportation personnel who delivers the shipment.

7.6.7.6 Record in the electronic manifest the date and time the receiving personnel takes custody of the shipment.

7.6.7.7 Enter the products containing marijuana into the inventory control system.

7.6.7.8 Segregate the items in the shipment from the inventory until the item can be inspected.

7.6.7.9 Inspect each item to ensure that the packaging of each item is undamaged, accurate and complete.

7.6.7.10 Upon determining the item passes inspection, release the item into the stock.

7.6.8 Transportation personnel must provide a copy of the electronic manifest for the shipment to the marijuana product manufacturing facility receiving delivery.

7.6.9 The transportation must provide the completed electronic manifest to the marijuana establishments conducting shipping.

7.6.10 The marijuana establishments conducting shipping must retain the electronic manifest for the shipment for a period of 5 years.

7.6.11 Discrepancies in shipments

7.6.11.1 A discrepancy between the electronic manifest and the shipment, must be reported to a supervisor.

7.6.11.2 If a discrepancy can be immediately rectified, the accepting manufacturer supervisor must record the rectification in the electronic manifest.

7.6.11.3 A discrepancy that cannot be immediately rectified must be reported to the Commissioner by the marijuana product manufacturing facility receiving delivery within 24 hours of the observation of the discrepancy. The marijuana establishment conducting the shipping must immediately investigate the discrepancy. The marijuana establishment conducting shipping must provide a preliminary report to the Commissioner within 7 business days of observation of the discrepancy, and a final report within 30 days.

7.6.12 Refusal of Shipment. In the event the marijuana establishment receiving delivery of a shipment refuses to take the delivery, it must immediately return the product to the source.

## 8.0 Marijuana and Marijuana Product Health Standards

8.1 Allowable and prohibited products

8.1.1 Allowable marijuana and marijuana products include:

8.1.1.1 Smokable marijuana, including shake, trim, pre-rolled marijuana, and infused pre-rolled marijuana;

8.1.1.2 Marijuana concentrates, including any type of hash (water hash, pressed hash), dry sieve (kief), and hash oils (extract oil, shatter, wax, resin, and rosin);

8.1.1.3 Non-smokable marijuana products intended for oral consumption, including edible marijuana products, multi-serving marijuana beverages, single-serving marijuana beverages, and tinctures;

8.1.1.4 Topical marijuana products, including balms, lotions, ointments, and rubbing alcohol solutions; and

8.1.1.5 Transdermal marijuana products, including patches.

8.1.2 Marijuana products not listed under subsection 8.1.1 of this regulation must be approved by the Commissioner.

8.1.3 Marijuana and marijuana products may not:

8.1.3.1 Contain nicotine;

8.1.3.2 Contain alcohol if the sale of the alcohol would require a license under 4 **Del.C.** Ch. 5;

8.1.3.3 Contain any non-cannabinoid additive that would increase potency, toxicity, or addictive potential;

8.1.3.4 Require refrigeration to prevent spoilage;

8.1.3.5 Contain compounds such as fruit filling, cream filling, or meat;

8.1.3.6 Take a shape, color, or character that is identical or substantially similar to commercially available candy or ice cream or a real or fictional person, animal, or fruit, including a caricature, cartoon, or artistic rendering; or

8.1.3.7 Be designed or packaged in a way that is likely to appeal to children, such as using bright, cartoon-like colors, shapes associated with children's products, or characters from children's media.

8.1.4 Equipment or accessories used for vaporizing marijuana concentrates must be coilless ceramic atomizers or similar products where the oil or concentrate does not touch metal coils.

8.1.5 Products developed for inhalation or vaping may not contain: medium-chain triglycerides (MCT), Polyethylene glycol (PEG), Propylene glycol (PG), Vegetable glycerin (VG), Vitamin E acetate, Diacetyl, or Squalene. Any diluent must be 100% naturally occurring plant-derived terpene oil.

8.2 Marijuana product serving size

8.2.1 For edible marijuana products, a standardized single serving of a marijuana product must contain no greater than 10 milligrams of THC.

8.2.2 For multi-serving marijuana beverages, contain no greater than 10 milligrams of THC.

8.2.3 For marijuana tinctures using a calibrated dropper or similar measuring device, contain no greater than 10 milligrams of THC per individual serving, as indicated on the calibrated dropper or similar measuring device.

8.2.4 A marijuana product manufacturer must:

8.2.4.1 Determine the total number of standardized servings for each marijuana product, which must not exceed 10 milligrams of THC per serving.

8.2.4.2 Ensure that each standardized serving of an edible marijuana product be physically demarcated or packaged in a manner that a person could reasonably and clearly determine how much of the product constitutes a single serving.

8.2.4.3 Ensure that each standardized serving is easily separable with minimal effort.

8.2.4.4 Comply with the requirements in Section 9.0 for multi-serving liquid edible marijuana products, which must not exceed 10 milligrams of THC per serving; and

8.2.4.5 For products containing multiple servings, ensure that each serving contains the same amount of THC.

8.3 Marijuana product package size

8.3.1 A standardized package of a marijuana product must:

8.3.1.1 For edible marijuana products, contain no greater than ~~5~~**[~~10~~5]** standardized servings per package;

8.3.1.2 For multi-serving marijuana beverages, contain no greater than ~~60~~**[~~100~~60]** milligrams of THC per package; and

8.3.1.3 For marijuana tinctures, contain no greater than ~~300~~ **[~~500~~ 300]** milligrams of THC per package.

8.3.2 Edible marijuana products formulated with less than ~~5~~**[~~10~~5]** standardized servings may package multiple products together to reach the ~~5~~**[~~10~~5]** serving maximum per package. Small individual products must comply with appearance standards in accordance with Section 9.0 of this regulation.

8.3.3 In accordance with Section 9.0 of this regulation, if a marijuana product package contains multiple servings, the package must be a child-resistant container that is resealable.

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## 9.0 Packaging and Labeling Requirements for Marijuana and Marijuana Products

9.1 General packaging requirements. All marijuana and marijuana products for retail sale must be packaged as follows:

9.1.1 If the packaging is soft sided, the opening must be sealed in a manner which would indicate if the container has been tampered with or opened. The tamper-evident feature shall not be resealable and shall remain clear that the package has been previously opened.

9.1.2 If the packaging is rigid, the opening shall contain a tamper-evident seal that, once opened, shall remain clear that the package has been previously opened.

9.1.3 The packaging must be child-resistant in accordance with 16 CFR 1700.15.

9.1.4 If the packaging is soft-sided, it must be 4 millimeters or greater in thickness.

9.1.5 If the packaging is rigid, it must have a lid or closure that can be placed tightly and securely.
9.1.6 If the marijuana product contains multiple servings, the packaging must be a child-resistant container that is resealable and must comply with subsection 9.3 if an edible marijuana product or beverage.
9.1.7 The marijuana product must be food-grade in quality and meet the food safety requirements in 16 **Del.C.** Ch. 33.

9.2 General labeling requirements
9.2.1 All marijuana and marijuana products for retail sale must be labeled in accordance with this regulation. All information on the label may not mislead consumers. All marijuana and marijuana product labels must:
9.2.1.1 Be printed directly on, or on a label or sticker affixed directly to, the marketing layer;
9.2.1.2 Include text no smaller than size 6 font or ½ inch;
9.2.1.3 Be legible, unobstructed, conspicuous, and contrast sufficiently with the background;
9.2.1.4 Be printed in the English language, but may also include translations in additional languages; and
9.2.1.5 Contain required information on a peel-back accordion-style, expandable, extendable, or layered label.
9.2.2 All marijuana and marijuana product labels must include the following product information:
9.2.2.1 The net weight of the marijuana or marijuana product in accordance with subsections 9.3, 9.4, and 9.5 of this regulation;
9.2.2.2 The finished product batch number;
9.2.2.3 If marijuana flower, the name of the marijuana establishment that cultivated, harvested, and packaged the marijuana flower;
9.2.2.4 If a marijuana product, the name of the marijuana establishment that manufactured and packaged the marijuana product;
9.2.2.5 The name of the marijuana establishment that sold the product;
9.2.2.6 An itemization, including weight, of the major cannabinoids and terpenes contained in the marijuana or marijuana product. Cannabinoids existing in concentrations of less than 1% shall be printed with a leading zero before the decimal point;
9.2.2.7 If a marijuana product, a list of all major allergens contained in and used in the manufacturing process in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, 21 U.S.C. §343, specifically including milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans;
9.2.2.8 A list of any solvents used in the manufacturing process;
9.2.2.9 The production date, which for flowers will be the date the marijuana was harvested and for product will be the date the product was produced; and
9.2.2.10 The Delaware Poison Control Center telephone number.
9.2.3 All marijuana and marijuana product labels must include the following warning statements:
9.2.3.1 "For use by adults 21+. KEEP OUT OF REACH OF CHILDREN!"
9.2.3.2 "Marijuana ingestion by children can cause severe illness and hospitalization. KEEP IN LOCKED STORAGE CONTAINERS."
9.2.3.3 "There may be health risks associated with the use of this product, and additional risks for women who are pregnant or breastfeeding or individuals 25 years of age and younger. Do not operate a motor vehicle or heavy machinery while using this product. The use of this product may result in adverse reactions with prescription medication, consult with your doctor or pharmacist."
9.2.4 All marijuana and marijuana product labels must include a universal symbol made available by the Commissioner. The universal symbol must:
9.2.4.1 Appear on the front of or the most prominently displayed area of the marketing layer;
9.2.4.2 Be printed in an area no smaller than ½ inch by ½ inch;
9.2.4.3 Contrast sufficiently with the background to be easily identified; and
9.2.4.4 Remain in the form provided by the Commissioner and shall not be modified, recreated, stylized, distorted, or otherwise altered in a manner that changes the appearance or size of the universal symbol.
9.2.5 Retail marijuana stores must retain copies of marijuana and marijuana product Certificate of Analyses and provide a copy to customers upon request.

9.3 Edible marijuana product and marijuana beverage packaging and labeling requirements
9.3.1 Edible marijuana product packaging must:
9.3.1.1 Contain no greater than 10 milligrams of THC per serving.
9.3.1.2 Contain no greater than 50 milligrams of THC per package; and
9.3.1.3 Clearly indicate the size of a serving.
9.3.1.4 If impracticable to clearly demark each serving of marijuana or to make each serving easily separable, contain not more than 10 milligrams of THC per package or be sold in a package that contains more than 1 individually wrapped single-serving edible marijuana product.
9.3.2 Marijuana beverage packaging must:

9.3.2.1 Contain no greater than 10 milligrams of THC and not less than 12 ounces of liquid per serving.
9.3.2.2 Contain no greater than 60 milligrams of THC per package; and
9.3.2.3 Clearly indicate the size of a serving.

9.3.3 In addition to requirements in subsection 9.2 of this regulation, edible marijuana product and marijuana beverage labels must include:

9.3.3.1 Total contents of THC and CBD, and any other advertised or marketed cannabinoid, stated in milligrams, as provided by the Certificate of Analysis. The total contents of THC and CBD must be provided for both individual servings and total servings within a package;

9.3.3.1.1 For edible marijuana products and marijuana beverages containing at least 5 milligrams of THC or CBD, there may not be a variance of more than 10% from the actual THC and CBD content.

9.3.3.1.2 For edible marijuana products and marijuana beverages containing less than 5 milligrams of THC or CBD, there may not be a variance of more than 20% from the actual THC and CBD content.

9.3.3.2 The number of servings per package;
9.3.3.3 If applicable, the recommended size of a serving;
9.3.3.4 A nutritional fact panel;
9.3.3.5 A list of all the active and inactive ingredients in descending order of predominance by weight in the edible marijuana product or marijuana beverage;
9.3.3.6 The net weight of the edible marijuana product or marijuana beverage in grams; and
9.3.3.7 The following warning statements:

9.3.3.7.1 A statement to read "Caution: When eaten or swallowed, the intoxicating effects of this product may be delayed by 2 or more hours."; and

9.3.3.7.2 For any product intended for topical application, a statement identifying that the product is "not intended for human consumption, ingestion, or inhalation."

9.4 In addition to requirements in subsection 9.2 of this regulation, inhalable marijuana product labels must include:

9.4.1 The product potency, which must be described by 1 of the following:

9.4.1.1 The actual potency results for total THC and total CBD reported by a testing facility on the Certificate of Analysis.

9.4.1.2 The percentage of total THC and total CBD based on the results of the analysis reported by a testing facility, and as the average percentage of total THC and total CBD found in the inhalable marijuana product, so long as the actual percentage totals of the THC and CBD content do not have a variance greater than 15% from the potency statement on the product label; or

9.4.1.3 If the Certificate of Analysis reports that the total THC or total CBD is "not detected" or "zero", the label may state "0" for these cannabinoids.

9.4.2 The net weight, which must be stated in grams, except that inhalable marijuana products containing less than 1 gram of net content may state the net contents in milligrams. In determining the weight of marijuana concentrate in a marijuana product, the weight of any other ingredients may not be included. Variance in net weight is allowed as follows:

9.4.2.1 For marijuana flower or trim, the actual net contents by weight may be as much as 0.1 grams less, or 0.5 grams greater than the net content on the label.

9.4.2.2 For pre-rolled marijuana, the actual net contents by weight may be as much as 5% less than or 10% more than the net content on the label.

9.4.2.3 For marijuana products composed primarily of marijuana concentrates or extract, the actual net contents by weight may be as much as 5% less or 10% more than the statement of net content.

9.5 Topical marijuana product and transdermal marijuana product packaging and labeling requirements

9.5.1 In addition to requirements in subsection 9.1 of this regulation, topical marijuana product and transdermal marijuana product packaging must:

9.5.1.1 Be packaged in a child-resistant container that has a resealable cap or closure compliant with 16 CFR 1700.15;

9.5.1.2 Transdermal marijuana products shall be packaged in a plastic container 4 millimeters or greater in thickness.

9.5.2 In addition to requirements in subsection 9.2 of this regulation, topical marijuana product and transdermal marijuana product labels must include:

9.5.2.1 A potency statement stating the total content of THC and CBD in milligrams in the container, and for transdermal marijuana products, the total content of THC and CBD in milligrams contained in each transdermal marijuana product;

9.5.2.2 The amount of the topical marijuana product or transdermal marijuana product recommended for use at any 1 time; and

9.5.2.3 A warning statement to read "For Topical Application Only-Do Not Eat or Smoke."

9.6 Marijuana establishments collecting samples for purposes of mandatory compliance testing must follow the following mandatory compliance procedures:

9.6.1 Deposit the sample into containers required by the marijuana testing facility analyzing the samples;

9.6.2 Affix a tamper evident seal to each sample container. The seal must be initialed by the Marijuana establishment staff which took the sample;

9.6.3 Ensure that the universal symbol is present every sample collection container, in accordance with the requirements in subsection 9.2.4 of this regulation;

9.6.4 Label each sample collection container with the following notice: "FOR TESTING PURPOSES ONLY"; and

9.6.5 Each sample collection container must be accompanied by a label generated by the seed-to-sale tracking system.

9.7 Marijuana and marijuana product packaging and labels may not contain the following:

9.7.1 Neon colors;

9.7.2 Imitation or resemblance of any existing branded consumer products;

9.7.3 Cartoons, cartoon-like fonts, caricatures, fruit, human or animal shapes, balloons or toys;

9.7.4 Depictions of a celebrity or celebrity likeness; or

9.7.5 Images of minors or words or images that refer to products that are commonly associated with minors or marketed to minors, including the word "candy."

9.8 Child Safety Measures

9.8.1 A retail marijuana store must provide with all marijuana and marijuana products sold at retail a written notification in at least 12-point font which contains the following warnings:

9.8.1.1 Marijuana ingestion by children can cause severe illness and hospitalization.

9.8.1.2 Marijuana products should be kept out of reach of children and in locked storage containers.

9.8.1.3 Allowing, through negligence or otherwise, children to ingest marijuana and marijuana products or storing marijuana and marijuana products in a location which is accessible to children may result in an investigation by an agency which provides child welfare services or criminal prosecution for child abuse or neglect.

9.8.1.4 Common signs and symptoms of marijuana ingestion in children are:

9.8.1.4.1 Dizziness;

9.8.1.4.2 Confusion;

9.8.1.4.3 Abnormal heart rate;

9.8.1.4.4 Sleepiness/Drowsiness;

9.8.1.4.5 Upset stomach;

9.8.1.4.6 Vomiting;

9.8.1.4.7 Diarrhea; and

9.8.1.4.8 Changes in breathing.

9.8.1.5 If your child collapses, appears to be having a seizure, or has difficulty breathing, contact 911 immediately.

9.8.2 A retail marijuana store must provide with all marijuana and marijuana products sold at retail safe drug storage educational information.

9.8.3 Each retail marijuana store shall offer for sale containers for the storage of marijuana and marijuana products which lock and are designed to prohibit children from unlocking and opening the container.

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## 10.0 Advertising

10.1 General advertising and marketing requirements

10.1.1 All advertisements and marketing materials must accurately and legibly identify all organizations or marijuana establishments responsible for the creation and proliferation of the advertisements or marketing materials.

10.1.2 All advertisements and marketing materials for marijuana or marijuana products that are viewable by the public must include all of the following health and safety statements:

10.1.2.1 Marijuana ingestion by children can cause severe illness and hospitalization. KEEP IN LOCKED STORAGE CONTAINERS."

10.1.2.2 "There may be health risks associated with the use of this product, and additional risks for women who are pregnant or breastfeeding or individuals 25 years of age and younger. Do not operate a motor vehicle or heavy machinery while using this product. The use of this product may result in adverse reactions with prescription medication, consult with your doctor or pharmacist."

10.1.2.3 "For use by adults 21+, KEEP OUT OF REACH OF CHILDREN!"

10.1.2.4 A statement that the product is not approved by the Federal Drug Administration (FDA) to treat, cure, or prevent any disease, and that the FDA has not evaluated the product for safety, effectiveness, or quality.

10.1.3 Marijuana establishments may not engage in advertising by means of television, radio, Internet, mobile application, social media, or other electronic communication, event sponsorship, or print publication, unless at least 85% of the audience is reasonably expected to be at least 21 years old as determined by reliable and current audience composition data.

10.1.3.1 A marijuana establishment must provide audience composition data to the Commissioner if requested. If the audience composition data provided to the Commissioner does not meet the requirements in this regulation, or if the marijuana establishment fails to immediately provide the requested audience composition data, the marijuana establishment must remove the advertisement or marketing material in question.

10.1.3.2 Each marijuana-related website shall employ a neutral age screening mechanism that verifies that the user is at least 21 years old, including by using an age-gate, age-screen, or age verification mechanism before the user may access or view any content and before the website may collect the user's address, e-mail address, phone number, or contact information to disseminate advertisements.

10.1.3.2.1 If a website is appropriate for a qualifying patient who is under the age of 21 years, the website shall provide an alternative screening mechanism for the qualifying patient.

10.1.3.2.2 An advertisement placed on social media or a mobile application shall include a notification that an individual must be at least 21 years old to view the content.

10.1.3.2.3 The provisions of this subtitle applicable to marijuana establishments may not be avoided by hiring or contracting with a third party, or outsourcing advertisements that do not comply with this subsection.

10.1.3.3 A marijuana establishment may not allow the use of its trademarks, brands, names, locations, or other distinguishing characteristics for third-party use for advertisements that do not comply with this subsection.

10.1.3.4 Violations of the requirements in this subsection may be subject to fines and penalties as provided for in Section 14.0 of this regulation.

10.2 Advertising and marketing prohibitions

10.2.1 Advertising and marketing of marijuana and marijuana products may not:

10.2.1.1 Be deceptive, misleading, false, fraudulent, or otherwise be conducted in a manner that typically deceives or misleads, whether directly or through ambiguity or omission;

10.2.1.2 Contain symbols or methods that are commonly used to market products to minors, including:

~~10.2.1.2.1 Neon colors;~~

~~10.2.1.2.2~~10.2.1.2.1 Imitation or resemblance of any existing branded consumer product;

~~10.2.1.2.3~~10.2.1.2.2 Cartoons, ~~cartoon-like fonts,~~ caricatures, ~~fruit, human or animal shapes,~~ balloons, or toys; or

~~10.2.1.2.4 Depictions of a celebrity or celebrity likeness; or~~

~~10.2.1.2.5~~10.2.1.2.3 Images of minors or words or images that refer to products that are commonly associated with minors or marketed to minors.

10.2.1.3 Use predatory advertising or marketing practices that target minors;

10.2.1.4 Be placed on the side of a building or another publicly visible location of any form, including a sign, a poster, a placard, a device, a graphic display, an outdoor billboard, or a freestanding signboard. This does not include exterior signage on the premises of the business for the limited purpose of identifying the business to the public and in compliance with subsection 10.2.3.

10.2.1.5 Occur on radio, television, other broadcast media, mass transit vehicles, or internet or app-based pop-ups, unless:

10.2.1.5.1 Subscribers of a subscription-based radio, television, or other broadcast media are 21 years of age or older; or

10.2.1.5.2 Individuals 21 years of age or older have solicited the advertising or marketing activities.

10.2.1.6 Occur through any paid or unpaid in-person solicitation of customers;

10.2.1.7 Imitate or resemble any existing branded consumer products;

10.2.1.8 Promote the overconsumption or irresponsible use of marijuana or marijuana products;

10.2.1.9 Depict the actual consumption of marijuana or marijuana products; or

10.2.1.10 Contain any health or physical benefit claims.

10.2.2 The Commissioner may consider ~~limited~~ exceptions to subsection 10.2.1.4 when petitioned in connection with ~~charitable or non-profit~~ charitable, non-profit, educational, or fundraising activities.

10.2.3 Signage displayed on the exterior of a marijuana establishment may not:

10.2.3.1 Contain a realistic depiction of a marijuana leaf; or

10.2.3.2 Be displayed in a size larger than 75 square feet or as limited by local ordinance, whichever is smaller.

10.3 Branding is not considered an advertising or marketing activity, and is not subject to the rules set forth in subsections 10.1 and 10.2 of this regulation, except that branding may not appeal to minors, and may not include:

~~10.3.1 Neon colors;~~

~~10.3.2~~10.3.1 Imitation or resemblance of any existing branded consumer product;

~~10.3.3~~10.3.2 Cartoons, ~~cartoon-like fonts,~~ caricatures, ~~fruit, human or animal shapes,~~ balloons, or toys; or

~~10.3.4 Depictions of a celebrity or celebrity likeness; or~~

~~10.3.5~~10.3.3 Images of minors or words or images that refer to products that are commonly associated with minors or marketed to minors.

10.4 Promotions and deals

10.4.1 Retail marijuana stores may not offer marijuana or marijuana products free of charge under any circumstance.

10.4.2 Marijuana or marijuana products may be discounted, provided that the discount is not made in conjunction with the retail sale of products other than marijuana.

10.4.3 Any promotion, deal, or discount on marijuana or marijuana products may not violate other advertising and marketing requirements of this regulation.

10.4.4 This subsection of rules is not applicable to promotions and deals offered to individuals holding a valid medical marijuana program card.

## 11.0 Testing and Sampling

11.1 Applicability

11.1.1 Prior to being transferred to a marijuana retail store, all marijuana and marijuana products must be tested by a marijuana testing facility licensed pursuant 4 **Del.C.** §1333.

11.1.2 A marijuana establishment that intends to transfer marijuana or marijuana products to a marijuana retail store is responsible for ensuring every required test is conducted in accordance with this section prior to transfer to the marijuana retail store.

11.1.3 The Commissioner may temporarily waive testing requirements for any analyte under this section if it is determined that public health and safety is not at risk.

11.1.4 The Commissioner may require immediate mandatory compliance testing under this regulation, including for any other analyte suspected to be a health hazard or safety threat, to ensure public health and safety.

11.2 Mandatory compliance testing. Marijuana testing facilities must test samples of marijuana and marijuana products for the following:

11.2.1 For pre-rolls, shake, trim, kief, and all other forms of marijuana flower:

11.2.1.1 Cannabinoid profile, including:

11.2.1.1.1 Tetrahydrocannabivarin (THCV);

11.2.1.1.2 Cannabidiol (CBD);

11.2.1.1.3 Cannabichromene (CBC);

11.2.1.1.4 Delta 8 Tetrahydrocannabinol (8-THC);

11.2.1.1.5 Delta 9 Tetrahydrocannabinol (9-THC);

11.2.1.1.6 Cannabigerol (CBG); ~~and~~

11.2.1.1.7 Cannabinol ~~(CBN).~~(CBN); and

11.2.1.1.8 The acid form of the above listed cannabinoids.

11.2.1.2 Foreign matter, including hair, insects, or similar adulterants.

11.2.1.3 Microbiological contaminants:

11.2.1.3.1 Aerobic bacterial;

11.2.1.3.2 Molds;

11.2.1.3.3 Yeast;

11.2.1.3.4 Coliform; and

11.2.1.3.5 *Escherichia coli*.

11.2.1.4 Heavy metals:

11.2.1.4.1 Lead;

11.2.1.4.2 Mercury;

11.2.1.4.3 Arsenic; and

11.2.1.4.4 Cadmium.

11.2.1.5 Terpenes

11.2.1.6 Pesticides

11.2.1.7 Total water activity

11.2.2 For marijuana concentrates, all testing requirements applicable to marijuana flower, as well as:

11.2.2.1 Butane;

11.2.2.2 Methanol;

11.2.2.3 Isopropanol;

11.2.2.4 Acetone;
11.2.2.5 1,1,1-Trichloroethane;
11.2.2.6 11,1-Dichloroethylene;
11.2.2.7 1,2-dichloroethane;
11.2.2.8 Carbon Tetrachloride;
11.2.2.9 Benzene;
11.2.2.10 Cyclohexane;
11.2.2.11 M-xylene;
11.2.2.12 Methylcyclohexane;
11.2.2.13 Trans-1,2-dichloroethylene;
11.2.2.14 Cis-1,2-dichloroethylene;
11.2.2.15 Toluene;
11.2.2.16 Tetrahydrofuran;
11.2.2.17 Methylene Chloride;
11.2.2.18 Acetonitrile;
11.2.2.19 1,4-Dioxane;
11.2.2.20 Ethylbenzene;
11.2.2.21 Chlorobenzene;
11.2.2.22 P-xylene;
11.2.2.23 Isopropyl benzene;
11.2.2.24 O-xylene;
11.2.2.25 Ethanol; and
11.2.2.26 Residual solvents.

11.2.3 For edible marijuana products, all testing requirements applicable to marijuana flower and marijuana concentrates, as well as validation of the stated cannabinoid content.

11.2.4 For inhalable or vaporizable marijuana products other than marijuana flower, all testing requirements applicable to marijuana flower and concentrates, as well as:
11.2.4.1 Medium-chain triglycerides (MCT);
11.2.4.2 Polyethylene glycol (PEG);
11.2.4.3 Vegetable glycerin (VG);
11.2.4.4 Vitamin E acetate;
11.2.4.5 Diacetyl; and
11.2.4.6 Squalene.

11.3 Testing failure thresholds. A sample of marijuana or marijuana products must be found to fail a laboratory test if it contains contaminants in quantities or concentrations as follows:

11.3.1 For foreign matter, including hair, insects, or similar adulterants, 1% or greater.

11.3.2 For microbiological contaminants:
11.3.2.1 Total Coliform, if detected;
11.3.2.2 *Escherichia coli*, if detected;
11.3.2.3 Molds; 400cfu/g or greater; and
11.3.2.4 Yeast, 400cfu/g or greater.

11.3.3 For heavy metals:
11.3.3.1 Lead, 0.5ppm or greater;
11.3.3.2 Mercury, 0.1ppm or greater;
11.3.3.3 Arsenic, 0.2ppm or greater; and
11.3.3.4 1 Cadmium, 0.2ppm or greater.

11.3.4 Pesticides, 10ppb or greater.

11.3.5 Residual solvents, if detected.

11.3.6 For additional contaminants:
11.3.6.1 Butane, if detected;
11.3.6.2 Methanol, if detected;
11.3.6.3 Isopropanol, if detected;
11.3.6.4 Acetone, if detected;
11.3.6.5 1,1,1-Trichloroethane, if detected;
11.3.6.6 1,1-Dichloroethylene, if detected;
11.3.6.7 1,2-dichloroethane, if detected;
11.3.6.8 Carbon Tetrachloride, if detected;
11.3.6.9 Benzene, if detected;
11.3.6.10 Cyclohexane, if detected;
11.3.6.11 M-xylene, if detected;
11.3.6.12 Methylcyclohexane, if detected;

11.3.6.13 Trans-1,2-dichloroethylene, if detected;
11.3.6.14 Cis-1,2-dichloroethylene, if detected;
11.3.6.15 Toluene, if detected;
11.3.6.16 Tetrahydrofuran, if detected;
11.3.6.17 Methylene Chloride, if detected;
11.3.6.18 Acetonitrile, if detected;
11.3.6.19 1,4-Dioxane, if detected;
11.3.6.20 Ethylbenzene, if detected;
11.3.6.21 Chlorobenzene, if detected;
11.3.6.22 P-xylene, if detected;
11.3.6.23 Isopropyl benzene, if detected;
11.3.6.24 O-xylene, if detected; and
11.3.6.25 Ethanol, 10% concentration or greater.

11.4 Sample collection procedures

11.4.1 The Commissioner will publish a Best Practices Guide for Sample Collection. All marijuana establishments collecting samples for mandatory compliance testing must comply with the Best Practices Guide.

11.4.2 Marijuana establishments must coordinate with the Division for the collection of samples. The samples must be randomly selected by the marijuana establishment, under the supervision of the Division, for each given batch of marijuana and marijuana products.

11.4.2.1 ~~In the case of emergency or extraordinary circumstances, the Commissioner may temporarily allow a marijuana establishment to self-sample and transport samples for mandatory compliance testing to a marijuana testing facility.~~ Division supervision may be done in person or samples in plain view of video surveillance cameras and in accordance with the requirements of this regulation and the Best Practices Guide for Sample Collection. Determination of method of supervision is at the discretion of the Division.

11.4.2.2 ~~In the event the Commissioner temporarily waives these requirements, a marijuana establishment must select samples in plain view of video surveillance cameras and in accordance with the requirements of this regulation and the Best Practices Guide for Sample Collection.~~ Transportation of samples from the marijuana establishment to the marijuana testing facility shall be carried out by the marijuana testing laboratory or the marijuana licensee whose product is being tested.

11.4.2.3 In the event that the marijuana testing facility or marijuana licensee utilizes a third-party for the transportation of samples, the individual transporting the marijuana must apply for registration with the Commissioner as if the individual is an employee of the marijuana testing facility, regardless of the actual employer.

11.4.3 Required sample sizes based upon matrix type and batch type are as follows:

11.4.3.1 Pre-rolls, shake, trim, kief, and all other forms of marijuana flower must be batch tested at approximately 0.25% of the batch weight, in accordance with TABLE 1 of this regulation.

11.4.3.1.1 Maximum flower batch weight is 10 pounds.
11.4.3.1.2 Minimum sample size is 3 grams.
11.4.3.1.3 Apportioned sample weights must be recorded on the manifest.

11.4.3.2 Marijuana concentrates must be batch tested at approximately 0.25% of the batch weight, in accordance with TABLE 1 of this regulation.

11.4.3.3 Marijuana product in individual retail units must be batch tested in accordance with TABLE 1 of this regulation.

TABLE 1: Example of Sample Size Based Upon Matrix Type and Batch Type:

| **Matrix Type** | **Batch Weight** | **Batch Units** | **Sample Amount (Portion)** |
|---|---|---|---|
| Marijuana Flower | ≤ 5lbs | | 3 grams |
| | 5.1lbs < w ≤ 10lbs | | 11 grams |

| | | | |
|---|---|---|---|
| Marijuana Concentrates | ≤ 1lbs | | 1.5 grams |
| | 1.1bls < w ≤ 2lbs | | 2 grams |
| | 2.1bls < w ≤ 3lbs | | 3 grams |
| | 3.1bls < w ≤ 4lbs | | 4 grams |
| | 4.1bls < w ≤ 5lbs | | 5 grams |
| Marijuana Products | | ~~1-250~~ | ~~1 unit~~ |
| | | ~~251-500~~Up to 500 | ~~2~~10 units |
| | | 501-1,000 | ~~4~~20 units |
| | | 1001-3,000 | ~~7~~35 units |
| | | 3,001-10,000 | ~~11~~55 units |
| | | >10,001 | ~~16~~80 units |

11.4.4 All edible marijuana products must be ~~packaged in accordance with subsection 9.3 of this regulation prior to sample collection. Depending on the number of units in the batch, at a minimum, 1 packaged unit for each edible marijuana product scheduled for testing, must be selected as a sample for mandatory compliance testing. The edible marijuana product will be collected in the final packaging for retail sale. The Commissioner shall require 1 unit sample for every product variety produced.~~submitted as individual, non-packaged units.

11.4.5 Marijuana establishments must ensure all samples for mandatory compliance testing and research and development purposes are packaged in accordance with Section 9.0 of this regulation.

11.4.6 Marijuana establishments must follow all tracking, transportation and record keeping requirements in accordance with Section 7.0 of this regulation.

11.5 Reporting requirements

11.5.1 For the purpose of testing, a marijuana testing facility must enter samples of marijuana and marijuana products, into the applicable laboratory section of the seed-to-sale tracking system.

11.5.2 The marijuana testing facility must enter mandatory compliance testing results into the seed-to-sale tracking system.

11.5.3 If a sample fails testing, the marijuana testing facility must report the failed test to both the Commissioner and the marijuana establishment that submitted the sample within 48 hours. The marijuana establishment that submitted the sample may retest or remediate and retest the batch in accordance with subsection 11.6 of this regulation.

11.5.4 If a sample passes testing, the marijuana testing facility must enter "pass" into the inventory seed-to-sale tracking system for the batch from which the sample came. The batch is then released for transfer to a marijuana retail store.

11.5.5 The marijuana testing facility is not required to report to the Commissioner the results of any tests if the requester notifies the marijuana testing facility in advance of transferring the sample of marijuana or marijuana product that the testing is for research development purposes and agrees not to use the results to satisfy any mandatory compliance testing requirements.

11.6 Retesting and remediation of failed marijuana or marijuana products

11.6.1 Batches of marijuana and marijuana products that have failed testing in accordance with subsection 11.3 of this regulation may be retested with or without remediation.

11.6.2 Edible marijuana products that fail initial testing may be re-tested 1 time. Any edible marijuana products that fail twice must be destroyed in accordance with Section 12.0 of this regulation.

11.6.3 A marijuana establishment seeking retesting of a batch that failed mandatory compliance testing without remediation must submit 2 samples from the batch that failed to the same marijuana testing facility that issued the initial failed test result.

11.6.3.1 Both samples submitted for retesting must pass all required testing required for any analyte that failed initial mandatory testing.

11.6.3.2 If either sample submitted for retesting fails any required test for any analyte that failed initial mandatory compliance testing, a batch of marijuana flower or trim may be transferred to a licensed marijuana manufacturing facility for extraction following a failed retest and subsequently tested in accordance with this regulation.

11.6.3.3 If either sample submitted for retesting fails any required test for any analyte that failed initial mandatory testing, the batch of marijuana concentrates, or marijuana products may not be remediated or retested and must be destroyed.

11.6.4 For marijuana establishments seeking retesting of a batch of marijuana or marijuana products that failed mandatory testing without remediation, the Division must submit the new samples from the batch that failed mandatory testing to the same marijuana testing facility that issued the initial failed test result.

11.6.5 A marijuana establishment may attempt to remediate any batch that fails mandatory testing, except for batches that fail due to pesticide contamination.

11.6.5.1 If a failed batch is remediated using a remediation method that does not change the marijuana or marijuana product into a different matrix of marijuana or marijuana product, then the marijuana establishment must submit 2 samples from the remediated batch to the same marijuana testing facility that issued the initial failed test result.

11.6.5.1.1 Both samples submitted for retesting must pass all required testing required for any analyte category that failed initial mandatory testing.

11.6.5.1.2 If either sample submitted for retesting fails any required test for any analyte category that failed initial mandatory testing, the batch of marijuana or marijuana products may be remediated in accordance with this section or destroyed.

11.6.5.2 If a failed batch is remediated using a remediation method that changes the marijuana or marijuana product into a different matrix of marijuana or marijuana product, then the marijuana establishment must submit 1 sample from the remediated batch to the marijuana testing facility that issued the initial failed test result.

11.6.5.2.1 The sample from the remediated batch must pass all mandatory testing required for the marijuana or marijuana product in the matrix it is in after remediation, including any tests previously passed, if applicable.

11.6.5.2.2 If the remediated batch, that is in a new matrix, fails mandatory compliance testing, the failed test is treated as an original failed mandatory compliance test and the remediated batch may be retested or remediated in accordance with this section.

11.6.6 If extraction is the remediation method and the marijuana or marijuana product must be transferred to a marijuana manufacturing facility, the licensed marijuana cultivation facility must first contact the Commissioner for approval.

11.6.7 Batches of marijuana flower or trim that have failed mandatory testing may not be remediated in a manner that involves the combination of the batch that failed testing with a batch, or batches, of marijuana flower or trim that has not been tested or that has passed testing.

11.6.8 Any retests of marijuana or marijuana products that failed initial testing are subject to the same testing requirements of the initial sample, except for heavy metals, if heavy metal testing passed in initial testing.

11.6.9 Any batches of marijuana and marijuana products that have failed initial testing where no remediation method is available must be destroyed in accordance with Section 12.0 of this regulation.

11.6.10 A marijuana establishment that remediates any failed batch must appropriately record all remediation steps and processes in the seed-to-sale tracking system. Approved remediation processes include pascalization, ozone, non-ionizing radiation, and ionizing radiation. Marijuana products exposed to

ionizing radiation must identify the exposure on package label in accordance with subsection 9.2 of this regulation.

11.6.11 A marijuana establishment must act to retest, remediate, or destroy a batch of marijuana or marijuana products within 30 days of receiving notice from the marijuana testing facility of the initial failed test result. If the marijuana establishment does not record an action on the failed batch within 30 days, the Commissioner may order destruction.

11.7 Testing for research and development purposes

11.7.1 Any marijuana establishment may submit samples of marijuana and marijuana products for research and development testing. Testing under this subsection does not have to comply with the mandatory compliance testing requirements of this regulation. Any sample transferred to a marijuana testing facility for testing purposes must be deemed a sample for research and development purposes prior to being transferred.

11.7.2 All samples for research and development testing must be transferred to a marijuana testing facility in accordance with Section 7.0 of this regulation.

11.7.3 The test results for the research and development sample may only be entered into the notes for a particular plant, batch, or barcodes within the seed-to-sale tracking system.

11.8 Test categories for marijuana and marijuana products

11.8.1 This subsection adopts and incorporates the following guidance on incorporated materials:

11.8.1.1 The Codex Alimentarius Commission, "General Guidelines on Sampling" CAC/GL50-2004 not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this regulation;

11.8.1.2 The Association of American Feed Control Officials (AAFCO) "Guidance on Obtaining Defensible Samples" or "GOODS" (2015) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this regulation; and

11.8.1.3 The U.S. Department of Agriculture, National Organic Program, "National Organic Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations" (2014), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this regulation.

11.8.2 Marijuana testing facilities may be approved to conduct testing as follows:

11.8.2.1 For pre-rolls, shake, trim, kief, and all other forms of marijuana flower:

11.8.2.1.1 Cannabinoid potency. A quantitative analysis including the amounts of cannabinoids present in accordance with subsection 11.2 of this regulation, expressed as a percentage of total cannabinoids present. Amounts of other cannabinoids may be reported but are not required;

11.8.2.1.2 Foreign matter. A quantitative analysis including the total amount of hair, insects, or similar adulterants present in accordance with this regulation;

11.8.2.1.3 Microbiological. A quantitative analysis including the total viable aerobic bacteria and total coliform present in accordance with this regulation;

11.8.2.1.4 Total water activity;

11.8.2.1.5 Pesticides. A quantitative analysis including the presence and amounts of residues of any pesticides or growth regulators in accordance with this regulation;

11.8.2.1.6 Metals. A quantitative analysis of the amounts of heavy metals present in accordance with this regulation; and

11.8.2.1.7 Residual solvents. A quantitative analysis of the presence and amounts of residual solvents in accordance with this regulation.

11.8.2.2 For marijuana concentrates, the same test categories as marijuana flower, as well as a quantitative analysis including the presence and amounts of any additional contaminants specified in subsection 11.2.2 of this regulation.

11.8.2.3 For edible marijuana products, the same test categories as marijuana flower and marijuana concentrates, as well as:

11.8.2.3.1 An analysis of the product's package to ensure it meets the requirements in Section 9.0 of this regulation; and

11.8.2.3.2 A quantitative analysis that validates the cannabinoid content stated on the product.

11.9 Sampling requirements

11.9.1 Marijuana testing facilities receiving samples from the Division must complete the chain of custody forms to record receiving and internal tracking of samples, including the following information:

11.9.1.1 The laboratory internal tracking number or other identification;

11.9.1.2 Printed name and signature of the person receiving the samples;

11.9.1.3 Date and time of sample receipt;

11.9.1.4 Condition of sample upon receipt;

11.9.1.5 Type of tests requested;

11.9.1.6 The name, address, and license number of the marijuana testing facility to which samples are forwarded for procedures not performed on the premises, each of which must be numbered or otherwise appropriately identified;
11.9.1.7 Sample tracking through each stage of storage, analysis, and disposal;
11.9.1.8 Date laboratory tests are performed;
11.9.1.9 The marijuana testing facility test results;
11.9.1.10 Date of reporting;
11.9.1.11 Sample test reports; and
11.9.1.12 The records of samples must contain the completed chain of custody forms and original completed sample collection forms.

11.9.2 Sample preparation. Each marijuana testing facility must adhere to the following:

11.9.2.1 Marijuana testing facilities must have a designated area of the facility dedicated to preparing marijuana and marijuana product samples for analysis. Sample preparation areas must be equipped with the supplies and equipment to properly handle samples during preparation, including:

11.9.2.1.1 Disposable gloves;
11.9.2.1.2 Decontaminated tools such as disposable pipettes and plastic or stainless-steel spatulas, knives, and sampling spears;
11.9.2.1.3 Decontaminated stainless-steel bowls and implements to homogenize the product by stirring, chopping, or grinding;
11.9.2.1.4 Clean, decontaminated surfaces for sample processing;
11.9.2.1.5 Decontaminated sample containers appropriate for the analyses required;
11.9.2.1.6 Container labels and pens with indelible ink; and
11.9.2.1.7 Supplies to thoroughly clean, decontaminate, and dry sample preparation equipment between samples.

11.9.2.2 Marijuana testing facilities must adhere to the following procedures when preparing each sample type:

11.9.2.2.1 Personnel handling samples must wear disposable gloves to avoid contamination and should not wear creams or perfumes.
11.9.2.2.2 Sample preparation area must be clean and decontaminated and tools and equipment laid out.
11.9.2.2.3 The sample must be placed in the stainless-steel bowl or on a decontaminated cutting surface for homogenizing the sample using either the sample collection tool or separate clean, decontaminated implement.
11.9.2.2.4 The sample must be prepared for analysis using an appropriate decontaminated tool. The sample should not be touched with bare hands or allowed to touch anything that might cause cross contamination.
11.9.2.2.5 Any tools or equipment that come in contact with the finished plant material or other marijuana or marijuana products must be cleaned before preparing the next sample.
11.9.2.2.6 All samples must be placed in clean, airtight sample containers that are large enough to hold the prescribed sample quantity with minimal headspace. Sample containers must be closed and labeled.
11.9.2.2.7 Samples must be refrigerated between 2-6º C to preserve the chemical and biological composition of the samples.
11.9.2.2.8 Ensure samples of marijuana and marijuana products are homogenous with respect to distribution of cannabinoids or contaminants.
11.9.2.2.9 Samples must be thoroughly stirred or mixed before quantitatively measuring for analysis. Solid and semi-solid products must be ground and thoroughly mixed. Grinding devices that minimize loss (e.g., leaching of resins) must be used and thoroughly cleaned after each use.
11.9.2.2.10 For marijuana and marijuana products that are distributed in a ground form, the product batch sample must be quartered. Quartering involves heaping the ground product, dividing the heap into 4 equal quarters, and selecting samples from 2 of the quarters, which are then combined and mixed. The remaining quarters may then be combined and mixed and used for microbiological and contaminant testing.
11.9.2.2.11 Resin and other solids may not be melted as a means of homogenization. Heating the product may alter the cannabinoid profile or contamination levels thereby rendering the sample unrepresentative of the source product.
11.9.2.2.12 Laboratory samples of edible marijuana products must be homogenized prior to testing so that the sample is representative of the finished product batch. Mix or quarter homogenized samples as described in subsection 11.9.2.2.10 of this regulation. If individually packaged edible marijuana products are sampled from a production batch, multiple packaged products

should be combined and prepared so that the distribution of cannabinoids or contaminants is representative of the production batch.

11.9.2.2.13 When subsamples are required, subsamples must be composited and mixed to obtain a quantity sufficient for evaluation. The quantity sufficient for evaluation may vary by analytical method and laboratory-specific procedures, therefore the marijuana testing facility must define the minimum sample quantity required for evaluation.

11.9.2.2.14 Compositing subsamples may be impractical for some product types (e.g., hard "candies" or other products in discrete solid units). In these cases, individual product units must be collected by the marijuana testing facility as samples for analysis. In some cases, the marijuana testing facility may combine extracts or digestates prepared from the solid subsamples and analyze the volumetrically combined extract/digestate as a composite.

11.9.3 Sample analysis. All marijuana and marijuana product samples described in this regulation must be analyzed by marijuana testing facilities licensed by the Commissioner. Each marijuana testing facility must:

11.9.3.1 Use only chemical standards manufactured by a provider acceptable to the Commissioner to prepare calibration and quality control standards;

11.9.3.2 Maintain standard preparation records and the certificates of analysis for all chemical standards, reference materials and reagents for at least 5 years; and

11.9.3.3 Demonstrate the ability to perform the quantitative analytical methods approved by the Commissioner, and to provide defensible documentation and quality assurance.

11.10 Approved methods and technical requirements for testing

11.10.1 Approved methods. Methods approved by the Commissioner for the analysis of cannabinoids and contaminants in marijuana and marijuana products are listed in Table 2. Equivalent test procedures may be followed if the marijuana testing facility has demonstrated the analysis is an acceptable alternative to normally used reference methods to the satisfaction of the Commissioner.

TABLE 2: List of Approved Methods for the Analysis of Cannabinoids and Contaminants

| Analytical Component | Methodology |
|---|---|
| D9-THC, D8-THC, THCA, CBD, CBDA | LC-DAD |
| CBC, CBCA, CBG, CBGA, CBN, CBNA | LC - MS, LC-MS/MS |
| | GC/ FID |
| Arsenic-Total mg/L | Digestion followed by ICP/MS |
| Cadmium-Total mg/L | Digestion followed by ICP/MS |
| | Digestion followed by Flame AA |
| | Digestion followed by Graphite Furnace |
| Lead-Total, mg/L | Digestion followed by ICP/MS |

| | |
|---|---|
| | Digestion followed by Flame AA |
| | Digestion followed by Graphite Furnace |
| Mercury-Total, mg/L | Digestion followed by ICP/MS |
| | Cold Vapor AA |
| Pesticides and Plant Growth Regulators - mg/L | QuEChERS, GC-MS, GC-MS/MS |
| | QuEChERS,LC-MS, LC- MS/MS |
| | QuEChERS GC-ECD, GC-NPD, LC-FLD |
| Water Activity | Humidity Meter, Hygrodynamic Hygrometer |
| Total Viable Aerobic Bacteria | Culture and enumeration |
| Total Yeast and Mold | Culture and enumeration |
| Total Coliforms | Culture and enumeration |
| Residual Solvents | Headspace GC/FID |

11.10.1.1 Table 2 Key:
- 11.10.1.1.1 AA = Atomic absorption
- 11.10.1.1.2 DAD = Photodiode-array detection
- 11.10.1.1.3 ECD = Electron capture detector
- 11.10.1.1.4 FLD = Fluorescence detector
- 11.10.1.1.5 FID = Flame ionization detector
- 11.10.1.1.6 GC = Gas chromatography
- 11.10.1.1.7 ICP = Inductively coupled plasma
- 11.10.1.1.8 LC = Liquid chromatography
- 11.10.1.1.9 MS = Mass spectrometry
- 11.10.1.1.10 NPD = Nitrogen phosphorous detector
- 11.10.1.1.11 QuEChERS = Quick, easy, cheap, rugged, and safe

11.10.1.2 Procedures and notes for Table 2:

11.10.1.2.1 A quantitative analysis must include the amounts of cannabinoids present in accordance with subsection 11.2 of this regulation, expressed as a percentage of total cannabinoids present. Amounts of other cannabinoids may be reported but are not required.

11.10.1.2.2 AHP. 2014. Cannabinoids by LC-Diode Array Detector, GC-Flame Ionization Detector or modified to use LC-Mass Spectrometer instead of LC-DAD. If GC/FID option is used, samples must be derivatized prior to analysis due to decarboxylation and degradation of the delta-9-THC

11.10.1.2.3 A digestion procedure is required to solubilize analytes in suspended material and to break down organic-metal complexes for determination of total metals (which are equivalent to total recoverable metals)

11.10.1.2.4 FDA Elemental Analysis Manual for Food and Related Products Section 4.3 "Graphite Furnace Atomic Absorption Spectrometric Determination of Cadmium and Lead in Food Using Microwave Assisted Digestion"

11.10.1.2.5 FDA Elemental Analysis Manual for Food and Related Products Section 4.5 "Cold Vapor Atomic Absorption Spectrometric Determination of Total Mercury in Seafood Using Microwave Assisted Digestion"

11.10.1.2.6 FDA Elemental Analysis Manual for Food and Related Products Section 4.7 "Inductively Coupled Plasma-Mass Spectrometric Determination of Arsenic, Cadmium, Chromium, Lead, Mercury, and other Elements in Food Using Microwave Assisted Digestion"

11.10.1.2.7 AOAC Official Method 2013.06 3- Arsenic, Cadmium, Mercury, and Lead in Foods - Pressure Digestion and Inductively Coupled Plasma-Mass Spectrometry (First Action 2013)

11.10.1.2.8 AOAC Official Method 2015.01 4- Heavy Metals in Food - Inductively Coupled Plasma-Mass Spectrometry (First Action 2015)

11.10.1.2.9 AOAC Official Method 999.1 Pb, Cd, Zn Cu, and Fe in Foods Atomic Absorption Spectrophotometry after Microwave Digestion (First Action 1999, Second Action 2005)

11.10.1.2.10 Second Supplement to USP 35-NF 30 (Chapter 233) Elemental Impurities Procedures

11.10.1.2.11 FDA KAN-LAB-PES.053. Analysis of Pesticides and Industrial Chemicals by the QuEChERS Procedure

11.10.1.2.12 AOAC Official Method 2007.01. Pesticide residues in foods by acetonitrile extraction and partitioning with Magnesium Sulfate

11.10.1.2.13 AOAC Official Method 2014.09. Determination and Confirmation of Residues of 653 Multiclass Pesticides and Chemical Pollutants in Tea

11.10.1.2.14 AOAC Official Method 998.01-2003 Synthetic pyrethroids in agricultural products.

11.10.1.2.15 USDA NOP 2611. Instructions for Laboratory Selection Criteria for Pesticide Residue Testing

11.10.1.2.16 EPA Index of Residue Analytical Methods (RAM)

11.10.1.2.17 Official Methods of Analysis of the AOAC. 978.18. Water Activity: 16th Edition,1995

11.10.1.2.18 FDA. 2001. Biological Analytical Manual. Chapter 3 Total Viable Aerobic Bacteria

11.10.1.2.19 FDA. 2015. Biological Analytical Manual. Chapter 18 Total Yeast and Mold

11.10.1.2.20 FDA. 2013. Biological Analytical Manual, Chapter 4 Enumeration of *Escherichia coli* and Coliform

11.10.1.2.21 FDA. 2016. Biological Analytical Manual, Chapter 4A Diarrheagenic *Escherichia coli*

11.10.1.2.22 FDA. 2016. Biological Analytical Manual, Chapter 5 Salmonella

11.10.1.2.23 USP. 2008. "Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests." USP 31, Chapter 61

11.10.1.2.24 USP. 2008. "Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms." USP 31, Chapter 62

11.10.1.2.25 USP. Undated-b. "Articles of Botanical Origin." USP 36, chapter 561

11.10.1.2.26 WHO 2007 guidelines for assessing quality of herbal medicines regarding contaminants and residues. Annex 5

11.10.1.2.27 1 USP. Chemical Tests. Chapter 467 Residual Solvents

11.10.2 Cannabinoid profile analysis additional information and requirements. All marijuana and marijuana products must be quantitatively analyzed following methods described in this regulation, to determine the total THC and its cannabinoid profile in the product. Although many cannabinoids and related compounds are present in the marijuana plant, characterization of the cannabinoid profile of the total THC in the marijuana product must include, at a minimum, the amounts of cannabinoids present in accordance with subsection 11.2.1.1 of this regulation, expressed as a percentage of total cannabinoids present. Amounts of other cannabinoids may be reported but are not required.

11.10.3 Heavy metal analysis additional information and requirements. Marijuana and marijuana products must be tested for metals including arsenic, cadmium, lead, and mercury following methods described in this regulation. Quantitative analyses of arsenic, cadmium, and lead must be performed using atomic

absorption spectrometry, inductively coupled plasma-optical emission spectrometry (ICP-OES) or ICP-mass spectrometry (ICP-MS). The analysis of mercury must be performed using cold vapor atomic absorption analysis (CVAA) or by ICP-MS. Analytical results which exceed these upper limits shall be reported with a qualifier indicating the contaminant measured in the marijuana or marijuana product is above the concentration allowable for the intended use. The analytical limit for marijuana products including marijuana and marijuana concentrates is specified in Table 3.

TABLE 3: Analysis Requirements for Metals in Marijuana and Marijuana Products for All Uses.

| METAL | ALL USES*<br><br>Upper Limit (ppm) | MARIJUANA-INFUSED PRODUCTS ONLY<br><br>Upper Limit (ppm) |
|---|---|---|
| Arsenic (inorganic) | <0.2 | <0.2 |
| Cadmium | <0.2 | <0.2 |
| Lead | <0.5 | <0.5 |
| Mercury | <0.1 | <0.1 |
| * These limits apply to finished marijuana plant material, marijuana resin, and marijuana concentrates intended for ingestion, inhalation, or dermal application. These limits are based on inhalation limits described in USP<232> Elemental Impurities-Limits. | | |

11.10.4 Pesticides residues analysis additional information and requirements. Marijuana testing facilities must conduct a quantitative analysis including the presence and amounts of residues of any pesticides or growth regulators in accordance with subsection 11.10.4 of this regulation. At a minimum, samples of marijuana or marijuana products must be tested for the pesticides, including plant growth regulators, included in Table 4 of this regulation, which includes the appropriate analytical methods for each of the listed pesticides. These pesticides were identified by AHP (2014) as commonly used in marijuana cultivation.

TABLE 4: Minimum Analysis Requirements for Residues of Pesticides and Plant Growth Regulators:

| PESTICIDE | CAS # | USE | RESIDUE ANALYTICAL METHODS |
|---|---|---|---|
| Abamectin (Avermectins B1a and B1b) | 71751-41-2 | Insecticide/acaricide | LC-FLD; LC-MS/MS |
| Acequinocyl | 57960-19-7 | Insecticide/acaricide | LC/MS/MS |

| | | | |
|---|---|---|---|
| Bifenazate | 149877-41-8 | Acaricide | LC; LC-MS/MS |
| Bifenthrin (synthetic pyrethroid) | 82657-04-3 | Insecticide | GC-ECD; GC-MS/MS LC-MS/MS |
| Chlormequat chloride | 7003-89-6 | Plant growth regulator | IC, LC-MS/MS |
| Cyfluthrin (synthetic pyrethroid) | 6859-37-5 | Insecticide | LC; GC-MS/MS; LC-MS/MS |
| Daminozide (Alar) | 1596-84-5 | Plant growth regulator | LC/UV; LC-MS/MS |
| Etoxazole | 153233-91-1 | Acaricide | GC-MS(/MS); LC-MS/MS |
| Fenoxycarb | 72490-01-8 | Insecticide | LCUV; LC-MS/MS |
| Imazalil | 35554-44-0 | Fungicide | GC-ECD; LC-MS/MS |
| Imidacloprid | 138261-41-3 | Insecticide | LC-MS/MS |
| Myclobutanil | 88671-89-0 | Fungicide | GC-ECD; GC-NPD; GSMS/MS; LC-MS/MS |
| Paclobutrazol | 76738-62-0 | Plant growth regulator; fungicide | LC-MS/MS |
| Spinosad | 168316-95-8 | Insecticide | LC-MS/MS |
| Spiromesifen | 283594-90-1 | Insecticide | GC-MS; LC-MS/MS |
| Spirotetramat | 20313-25-1 | Insecticide | LC/LC-MS/MS |
| Trifloxystrobin | 141517-21-7 | Fungicide | GC-NPD; GC-MS/MS; LCMS/MS |

| | | | |
|---|---|---|---|
| Acequinocyl | 57960-19-7 | Insecticide/acaricide | LC/MS/MS |
| Bifenazate | 149877-41-8 | Acaricide | LC; LC-MS/MS |
| Bifenthrin (synthetic pyrethroid) | 82657-04-3 | Insecticide | GC-ECD; GC-MS/MS LC-MS/MS |
| Chlormequat chloride | 7003-89-6 | Plant growth regulator | IC, LC-MS/MS |
| Cyfluthrin (synthetic pyrethroid) | 6859-37-5 | Insecticide | LC; GC-MS/MS; LC-MS/MS |
| Daminozide (Alar) | 1596-84-5 | Plant growth regulator | LC/UV; LC-MS/MS |
| Etoxazole | 153233-91-1 | Acaricide | GC-MS(/MS); LC-MS/MS |
| Fenoxycarb | 72490-01-8 | Insecticide | LC/UV; LC-MS/MS |
| Imazalil | 35554-44-0 | Fungicide | GC-ECD; LC-MS/MS |
| Imidacloprid | 138261-41-3 | Insecticide | LC-MS/MS |
| Myclobutanil | 88671-89-0 | Fungicide | GC-ECD; GC-NPD; GSMS/MS; LC-MS/MS |
| Paclobutrazol | 76738-62-0 | Plant growth regulator; fungicide | LC-MS/MS |
| Spinosad | 168316-95-8 | Insecticide | LC-MS/MS |
| Spiromesifen | 283594-90- | Insecticide | GC-MS; LC-MS/MS |
| Spirotetramat | 20313-25-1 | Insecticide | LC/LC-MS/MS |

| | | | |
|---|---|---|---|
| Trifloxystrobin | 141517-21-7 | Fungicide | GC-NPD; GC-MS/MS; LCMS/MS |

11.10.4.1 Table 4 Key:
- 11.10.4.1.1 ECD = Electron capture detector
- 11.10.4.1.2 FLD = Fluorescence detector
- 11.10.4.1.3 GC = Gas chromatography
- 11.10.4.1.4 MS = Mass spectrometry
- 11.10.4.1.5 NPD = Nitrogen phosphorous detector
- 11.10.4.1.6 LC = Liquid chromatography

11.10.4.2 Marijuana testing facilities must analyze pesticides in addition to those in Table 4 based on the approach that USDA uses to analyze 195 prohibited pesticides it has targeted in organic food. With the understanding that no single analytical method currently exists to analyze all 195 prohibited pesticides, marijuana testing facilities conducting marijuana testing in Delaware must analyze as many compounds on the USDA target analyte list for organic food as possible. Analytical laboratories must follow procedures listed in this regulation or their equivalents.

11.10.4.3 The upper limit for pesticides and plant growth regulators is less than or equal to 10 parts per billion (ppb).

11.10.4.4 A marijuana testing facility that is unable to perform the required testing of pesticide residues at or below the 10 parts per billion (ppb) criteria may determine compliance by ensuring that any pesticide residues are present at a level less than or equal to 5% of the US EPA tolerance for the specific residue. EPA pesticide tolerances are available from Title 40 of the Code of Federal Regulations (C.F.R.). In these circumstances, the Commissioner must be notified regarding the specific pesticides to which this method is being applied.

11.10.5 Water activity analysis additional information and requirements. Pre-rolls, shake, trim, kief, and all other forms of marijuana flower shall be tested for water activity following methods described in this regulation. The water activity upper limit for unbound water is equal to or less than 0.6aW.

11.10.6 Microbiological contaminants analysis additional information and requirements. Marijuana flower, pre-rolls, shake, trim, kief, and all other forms of raw marijuana must be tested for microbiological contaminants following methods described in this regulation. Methods used must be consistent with the following United States Pharmacopeia Chapters: USP Chapter < 61>: Microbiological Examination of Non-sterile Products: Microbial Enumeration Tests. USP 36, Chapter 6 and USP Chapter < 62>: Microbiological Examination of Non-sterile Products: Tests for specified Microorganisms. USP 36, Chapter 62. Limits for microbiological contaminants are listed in Table 5.

TABLE 5: Upper Limits for Microbiological Contaminants

| MARIJUANA MATERIAL | TOTAL VIABLE AEROBIC BACTERIA (CFU*/g) | TOTAL YEAST AND MOLD (CFU/g) | TOTAL COLIFORMS AND Escherichia coli (CFU/g) | AFLATOXINS (B1, B2, G1, G2) | OCHRATOXIN A |
|---|---|---|---|---|---|
| Finished plant material | 400 CFU/g | 400 CFU/g | IF DETECTED | < 20 ppb | < 20 ppb |
| * CFU means colony forming unit. | | | | | |

11.10.7 Use of Validated Nucleic Acid Amplification (NAAT), Molecular and Immunological Assays. Marijuana flower, pre-rolls, shake, trim, kief, and all other forms of raw marijuana may also be tested for microbiological contaminants using a validated molecular or immunological analytical method, including nucleic acid amplification tests (NAATs), enzyme-linked immunosorbent assays (ELISA), or other antibody-based detection platforms approved by the Commissioner. A licensee may elect to perform a validated molecular or antibody-based assay test as the initial test or as a retest for marijuana or

marijuana products that fail to meet the upper limits for microbiological contaminants stated in Table 5. When tested in accordance with this subsection, marijuana and marijuana products will be held to the microbiological contaminant levels listed in Table 6:

TABLE 6: Expanded Limits for NAAT Tested Products

| TARGET CONTAMINANT | UPPER LIMITS |
|---|---|
| Aspergillus (flavus, fumigatus, niger, terreus) | IF DETECTED |
| Salmonella spp. | IF DETECTED |
| Shiga toxin-producing E. coli (STEC) | IF DETECTED |
| Pseudomonas aeruginosa | IF DETECTED |
| Staphylococcus aureus | IF DETECTED |
| Aflatoxins | < 20 ppb |
| Ochratoxin | < 20 ppb |
| Total Yeast & Mold (TYM) | 100,000 CFU/g (Flower)<br>10,000 CFU/g (Extracts) |
| Total Viable Aerobic Bacteria | 100,000 CFU/g (Flower)<br>10,000 CFU/g (Extracts) |

11.10.8 Residual solvent analysis additional information and requirements. Marijuana concentrates must be tested for residual solvents when solvents have been used in the production process following methods described in this regulation. Marijuana testing facilities are required to test for the residual solvents listed in Table ~~6~~7 of this regulation, unless it can document that no solvents were used in the marijuana concentrate production process:

TABLE ~~6:~~7: Analysis Requirements for Residual Solvents

| SOLVENT | CAS # | UPPER LIMIT (mg/kg)* | SOLVENT | CAS # | UPPER LIMIT (mg/kg)* |
|---|---|---|---|---|---|
| Acetone | 67-64-1 | 5000 | Heptane | 142-82-5 | 5000 |
| Acetonitrile | 75-05-8 | 410 | Hexane | 110-54-3 | 290 |
| Benzene ** | 71-43-2 | 2 | Isobutane | 75-28-5 | 5000 |
| Butane | 106-97-8 | 5000 | Isopropyl acetate | 108-21-4 | 5000 |
| 1-Butanol | 71-36-3 | 5000 | Methanol | 67-56-1 | 3000 |
| 2-Butanol | 78-92-2 | 5000 | Methylbutylketone | 591-78-6 | 50 |
| 2-Butanone | 78-93-3 | 5000 | Methylcyclohexane | 108-87-2 | 1180 |
| Carbon | 56-23-5 | 4 | Methylethylketone | 78-93-3 | 5000 |

| | | | | | |
|---|---|---|---|---|---|
| tetrachloride** | | | | | |
| Cumene | 98-82-8 | 70 | Methylisobutylketone | 108-10-1 | 5000 |
| Cyclohexane | 110-82-7 | 3880 | Methylpropane | 75-28-5 | 5000 |
| 1,2-Dichlorethane** | 107-06-2 | 5 | 2-Methyl-1- propanol | 78-83-1 | 5000 |
| 1,1-Dichloroethene** | 75-35-4 | 8 | 2-Methylbutane | 78-78-4 | 5000 |
| 1,2-Dichloroethene | 540-59-0 | 1870 | 2-Methylpentane | 107-83-5 | 290 |
| Dichloromethane | 75-09-2 | 600 | 3-Methylpentane | 96-14-0 | 290 |
| 1,2-Dimethoxyethane | 110-71-4 | 100 | N-Methylpyrrolidone | 872-50-4 | 530 |
| 1,2-Dimethylbenzene | 95-47-6 | 2170 | Nitromethane | 75-52-5 | 50 |
| 1,3-Dimethylbenzene | 108-38-3 | 2170 | Pentane | 109-66-0 | 5000 |
| 1,4-Dimethylbenzene | 106-42-3 | 2170 | 1-Pentanol | 71-41-0 | 5000 |
| 2,2-Dimethylbutane | 75-83-2 | 290 | 1-Propanol | 71-23-8 | 5000 |
| 2,3-Dimethylbutane | 79-29-8 | 290 | 2-Propanol | 67-63-0 | 5000 |
| N,N-Dimethylacetamide | 127-19-5 | 1090 | Propane | 74-98-6 | 5000 |

| | | | | | |
|---|---|---|---|---|---|
| N,N-Dimethylformamide | 68-12-2 | 880 | Propyl acetate | 109-60-4 | 5000 |
| Dimethyl sulfoxide | 67-68-5 | 5000 | Pyridine | 110-86-1 | 200 |
| 1,4-Dioxane | 123-91-1 | 380 | Sulfolane | 126-33-0 | 160 |
| Ethanol | 64-17-5 | 5000 | Tetrahydrofuran | 109-99-9 | 720 |
| 2-Ethoxyethanol | 110-80-5 | 160 | Tetralin | 119-64-2 | 100 |
| Ethyl acetate | 141-78-6 | 5000 | Toluene | 108-88-3 | 890 |
| Ethylbenzene | 100-41-4 | 70 | 1,1,1-Trichloroethane** | 71-55-6 | 1500 |
| Ethylene glycol | 107-21-1 | 620 | 1,1,2-Trichloroethylene | 79-01-6 | 80 |
| Ethylene oxide | 75-21-80 | 50 | Xylene | 1330-20-7 | 2170 |
| Ethyl ether | 60-29-7 | 5000 | 1,1,2-Trichloroethylene | 79-01-6 | 80 |
| * See Section 6.0 of this regulation for further information. | | | | | |
| ** Class 1 solvents provided by USP Chapter <467> shall not be used in the production of any marijuana or marijuana product. | | | | | |

~~11.10.7.1~~11.10.8.1 The upper limits for residual solvents in Table ~~6~~7 are given as milligrams of residual solvent per kilogram of marijuana concentrate. The upper limits in Table ~~6~~7 are based on residual solvent standards provided by the USP Chapter < 467>, the International Conference on Harmonization (ICH, 2011), and AHP (2014).

~~11.10.7.2~~11.10.8.2 Class 1 solvents shall not be used in the production of any marijuana or marijuana product.

~~11.10.7.3~~11.10.8.3 Analyses to determine residual solvent concentrations in marijuana or marijuana products must be performed in accordance with the methods identified in USP Chapter < 467>.

~~11.10.7.4~~11.10.8.4 Any detection of solvents at any level must be reported to customers.

~~11.10.8~~11.10.9 Quality control. Marijuana testing facilities must prepare and analyze samples in batches of up to 20 samples that include a laboratory reagent blank, a laboratory fortified blank, a sample duplicate, and a laboratory fortified sample for chemical tests.

~~11.10.8.1~~11.10.9.1 For initial calibration, the analytical sequence must include initial and continuing instrument calibrations performed per the approved method requirements. If the approved method does not specify calibration requirements, then marijuana testing facilities must at a minimum perform a 3-point initial calibration spanning a concentration range from below to above the maximum allowable contaminant concentration. Marijuana testing facilities are required to achieve a linear response for all cannabinoids, metals, and pesticides analyses. The initial calibration for each analyte must have a relative standard deviation of 15% or a correlation factor of 0.995.

~~11.10.8.2~~11.10.9.2 For continuing calibration, if approved analytical methods do not specify calibration requirements, the analytical sequence must include a continuing calibration standard and continuing calibration instrument blank before and after every 10 samples (including quality control samples). The percent difference of the continuing calibration response for all analytes must be equal to or less than 15% compared to the expected continuing calibration standard response. Marijuana testing facilities must document the calibration performance and quality control results for all analyses.

~~11.10.8.3~~11.10.9.3 For quality control secondary, all calibrations must be verified with a standard obtained from a second manufacturer or a separate lot prepared independently by the same manufacturer at least quarterly. This verification is performed by analyzing a test solution of known analyte concentration after calibration and prior to sample analysis. Verification must be +/-20% of the known value.

~~11.10.9~~11.10.10 Test reporting. Marijuana testing facilities must:

~~11.10.9.1~~11.10.10.1 Report all testing results including all information necessary to determine product compliance to the Commissioner and the marijuana or marijuana product producer, including marijuana product manufacturers, marijuana micro-businesses, and marijuana cultivators.

~~11.10.9.2~~11.10.10.2 Include the following in the laboratory data package:

~~11.10.9.2.1~~11.10.10.2.1 A case narrative, written on marijuana testing facility letterhead, must describe any sample receipt, preparation, or analytical issues encountered as well as any method non-conformances or exceedance of quality assurance or quality control criteria used by the marijuana testing facility. The narrative must identify the preparation and analytical methods utilized by the marijuana testing facility. The narrative must include a signed statement by an authorized marijuana testing facility representative as to the accuracy, completeness, and compliance with the methods of the results presented;

~~11.10.9.2.2~~11.10.10.2.2 Chain-of-custody information or other paperwork indicating requested analyses and documentation of sample collection and receipt must be reported with the marijuana testing facility's results;

~~11.10.9.2.3~~11.10.10.2.3 Marijuana testing facility reports must clearly identify the name, address, and license number of the marijuana testing facility that performed the test and must include the results and the date of the reporting;

~~11.10.9.2.4~~11.10.10.2.4 Multipage reports must be paginated;

~~11.10.9.2.5~~11.10.10.2.5 A summary of analytical results including sample identifier, methods performed, target compounds, sample result or reporting limit, proper qualifier according to laboratory standard procedures, units of measure, preparation dates, where applicable, and analysis dates;

~~11.10.9.2.6~~11.10.10.2.6 Analytical results which exceed the upper limit described in this regulation must be reported with a qualifier indicating the contaminant measured in the marijuana or marijuana product is above the allowable concentration; and

~~11.10.9.2.7~~11.10.10.2.7 The marijuana testing facility data package must include sufficient data to evaluate the laboratory results, including a summary of laboratory quality assurance or quality control results.

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## 12.0 Waste and Disposal

12.1 General waste and disposal requirements. All wastes which are not classified as marijuana wastes, medical wastes, or hazardous wastes, or which are not otherwise regulated by law or regulation, must be managed by disposing in dumpsters or load packers with the following protocols:

12.1.1 Dumpsters must be tightly covered, leak proof, inaccessible to rodents and animals, and placed on concrete slabs preferably graded to a drain. Water supply must be available within easy accessibility for

washing-down of the area. More frequent waste pickups must be scheduled when required. The dumping site of waste materials must be in sanitary landfills approved by DNREC.

12.1.2 Load packers must conform to the same restrictions required for dumpsters and must be high enough off the ground to facilitate the cleaning of the underneath areas of the stationary equipment. The loading section must be constructed and maintained in a way to prevent rubbish from blowing away.

12.1.3 Dumpsters and load packers must be secured in a manner to prevent unauthorized access to the marijuana waste.

12.2 Destruction of marijuana waste

12.2.1 All marijuana waste must be rendered unusable before leaving a marijuana establishment by grinding and incorporating the marijuana waste with non-consumable solid wastes such that the resulting mixture is no greater than 50% marijuana waste. Non-consumable solid waste includes:

12.2.1.1 Paper waste;

12.2.1.2 Plastic waste;

12.2.1.3 Cardboard waste;

12.2.1.4 Food waste;

12.2.1.5 Soil;

12.2.1.6 Grease or other compostable waste; and

12.2.1.7 Other non-consumable solid wastes approved by the Commissioner.

12.2.2 When a marijuana plant, marijuana, or marijuana product is removed from inventory for destruction, the marijuana establishment must:

12.2.2.1 Immediately update inventory in the seed-to-sale tracking system;

12.2.2.2 Quarantine the marijuana plant, marijuana, or marijuana product for 72 hours before destruction; and

12.2.2.3 Notify the Commissioner of the pending destruction.

12.2.3 The Commissioner may choose to observe in person any destruction of any marijuana waste.

12.2.4 Destruction of marijuana plants, marijuana, or marijuana products must occur when and where the action of the marijuana establishment can be clearly captured by video surveillance, in accordance with Section 6.0 of this regulation.

12.2.5 All destruction records must be made available for auditing by the Commissioner.

12.3 Disposal of marijuana waste

12.3.1 After marijuana waste is rendered unusable, the solid waste must be:

12.3.1.1 Disposed of at a solid waste disposal site or disposal facility that has a Certificate of Designation from the applicable local governing body;

12.3.1.2 Deposited at a compost facility that has a Certificate of Designation from DNREC;

12.3.1.3 Composted on the licensed premises of the marijuana establishment who generated the waste, and in accordance with applicable federal, state, and local requirements; or

12.3.1.4 Disposed of in dumpsters or load packers in accordance with subsection 12.1 of this regulation.

12.3.2 Liquid marijuana waste must be disposed of in accordance with applicable federal, state, and local requirements, and the International Plumbing Code.

## 13.0 Retail Marijuana Tax

13.1 Collection and rate

13.1.1 The Retail Marijuana Tax imposed on the consumer under 4 **Del.C.** §1382 must be collected at the point of sale, held in trust, and remitted to Revenue by each licensee of a retail marijuana store that engages in the retail sale of marijuana products.

13.1.2 The Retail Marijuana Tax is considered a tax upon the retail marijuana store licensee that is required to collect the tax, and the retail marijuana store licensee is considered the taxpayer.

13.1.3 The Retail Marijuana Tax rate is the rate set forth in 4 **Del.C.** §1382(b).

13.1.4 The Retail Marijuana Tax collected each month consists of the total amount of retail sales of marijuana products for that month multiplied by the Retail Marijuana Tax rate as calculated on the Retail Marijuana Tax Form. If the tax imposed under this section does not equal an amount calculable to a whole cent, the tax is equal to the next higher whole cent.

13.1.5 The Retail Marijuana Tax imposed on the retail sale of marijuana products under 4 **Del.C.** §1382 shall not be imposed on an individual with a medical marijuana program card.

13.2 Submission of Retail Marijuana Tax Form

13.2.1 Each month every retail marijuana store licensee must file with Revenue a Retail Marijuana Tax Form, which is due on or before the 15th day of the following month.

13.2.2 When the due date falls on a Saturday, Sunday, or a state legal holiday, the Retail Marijuana Tax Form is due on the next business day following the Saturday, Sunday, or state legal holiday.

13.2.3 Each retail marijuana store must file a Retail Marijuana Tax Form every month, even if it:

13.2.3.1 Is not required to remit payment of any Retail Marijuana Tax for that month; or

13.2.3.2 Does not make any sales of marijuana products for that month.

13.2.4 Retail marijuana tax forms must be electronically filed with Revenue on the Delaware Taxpayer Portal.

13.3 Payment

13.3.1 Each retail marijuana store licensee must pay the Retail Marijuana Tax due on or before the 15th day of each month with respect to the sales of marijuana products for the immediately preceding month.

13.3.2 When the due date falls on a Saturday, Sunday, or a state legal holiday, the payment is due on the next business day following the Saturday, Sunday, or state legal holiday.

13.4 Delaware Taxpayer Portal

13.4.1 Retail marijuana tax due to the State of Delaware reported on the Retail Marijuana Tax Form must be verified, computed, and paid electronically on the Delaware Taxpayer Portal. The Delaware Taxpayer Portal is be located at https://tax.delaware.gov.

13.4.2 Taxpayers who do not already have a Delaware Taxpayer Portal account should create a Delaware Taxpayer Portal account at least 96 hours before the Retail Marijuana Tax Form is due.

13.5 Liability for unpaid Marijuana Tax

13.5.1 Except to the extent inconsistent with this regulation or Chapter 13 of Title 4 of the Delaware Code, any retail marijuana store which fails to file a Retail Marijuana Tax Form or pay the Retail Marijuana Tax when due is subject to penalties as any other taxpayer. The provisions of Chapter 5 of Title 30 of the Delaware Code shall govern the assessment, collection, review, and appeal of deficiencies of tax imposed by Title 4 of the Delaware Code, and any interest and penalties thereon.

13.5.2 The Commissioner or Division may impose additional penalties or take other enforcement actions, including suspension or cancellation of the retail marijuana store's license.

13.5.3 If a retail marijuana store fails to timely pay any Retail Marijuana Tax due, there shall be added to the tax an amount equal to 1% of the tax required to be shown on the return for each month, or fraction thereof, during which the failure continues, not exceeding 25% in the aggregate.

13.5.4 In addition to the retail marijuana store, each responsible person who willfully fails to collect or truthfully account for and pay over the tax, or willfully attempts in any manner to evade or defeat any tax or the payment thereof, shall, in addition to other penalties provided by law, be liable for the total amount of the tax evaded, or not collected, or not accounted for and paid over, including interest and penalties.

13.6 A retail marijuana store must provide customers a printed or electronic receipt at the time any retail sale of marijuana products occurs that includes:

13.6.1 The retail marijuana store's business name and address;

13.6.2 An identification of items or products on which tax was charged.

13.6.3 The total amount of retail marijuana tax, which must be separately stated;

13.6.4 The total cost to the customer at the point-of-sale;

13.6.5 The category of taxed product or the product category used in the seed-to-sale tracking system for each item or product sold, either as a heading for a group of items or products or as information associated with the item or product name;

13.6.6 Information sufficient to identify the original transaction, which could be either:

13.6.6.1 The date and time of the transaction, the register from which the transaction was conducted, or the name or employee identification number of the employee who tendered the sale; or

13.6.6.2 A unique alphanumeric identifier.

13.7 Each marijuana establishment and responsible person must provide the Commissioner with a Certificate of Tax Clearance for corporate and personal income taxes. Information on obtaining a Certificate of Tax Clearance may be found at: https://revenue.delaware.gov/business-tax-forms/certificate-of-tax-clearance.

13.8 Recordkeeping and retention for Retail Marijuana Tax

13.8.1 Tax recordkeeping requirements

13.8.1.1 Retail marijuana stores must maintain all records and any information and data required to be entered into the seed-to-sale tracking system that are necessary to determine the correct tax liability under 4 **Del.C.** §1382(b). All required records must be made available on request by Revenue or its authorized representatives.

13.8.1.2 Retail marijuana stores must maintain records of all tax-exempt sales of marijuana products to the holders of a registry identification card issued under Chapter 49A of Title 16 of the Delaware Code.

13.8.1.3 These records must include:

13.8.1.3.1 The date of the sale;

13.8.1.3.2 The medical marijuana program card number;

13.8.1.3.3 The taxed marijuana product category, or the product category used in the seed-to-sale tracking system;

13.8.1.3.4 The name of the marijuana product;

13.8.1.3.5 The unit price of the marijuana product;

13.8.1.3.6 The number of units sold; and

13.8.1.3.7 The total amount of the sale.

13.8.1.4 If a retail marijuana store retains required records in both electronic and hard-copy formats, the retail marijuana store must make the records available to Revenue in electronic format upon request.

13.8.1.5 Nothing in this regulation shall be construed to prohibit a retail marijuana store from demonstrating tax compliance with traditional hard-copy documents.

13.8.2 Retail marijuana store responsibility and discretionary authority

13.8.2.1 A retail marijuana store may create files solely for the use of Revenue. For example, if a data base management system is used, it is consistent with this regulation for the retail marijuana store to create and retain a file that contains the transaction-level detail from the data base management system and that meets the requirements of Section 7.0 of this regulation. The retail marijuana store should document the process that created the separate file to show the relationship between that file and the original records.

13.8.2.2 A retail marijuana store may contract with a third party to provide custodial or management services for the records. Such a contract shall not relieve the retail marijuana store of its responsibilities under this regulation.

13.9 With the exception of the retail sale of marijuana products, marijuana establishments are required to maintain or possess all business or other licenses required by Title 30 of the Delaware Code.

**14.0 Enforcement, Fines, and Penalties**

14.1 Enforcement activities

14.1.1 The Division shall be responsible for enforcement of the Act and this regulation.

14.1.2 The Division shall conduct administrative inspections of marijuana establishments to ensure compliance with the Act.

14.1.3 The Division will provide a summary of deficiencies recorded during an inspection or investigation to the marijuana establishment.

14.1.3.1 The marijuana establishment may be required to provide a plan of corrective action, including expected completion dates for the correction of all deficiencies listed, within a time proscribed by the Division.

14.1.3.2 A follow-up inspection may be conducted to ensure that all deficiencies have been corrected.

14.2 Commissioner actions

14.2.1 Whenever the Commissioner finds a marijuana establishment guilty of a violation of the Act or this regulation, the Commissioner shall have the power and authority to take any of the following actions alone or in combination:

14.2.1.1 Impose a fine

14.2.1.2 Suspend a license

14.2.1.3 Cancel a license

14.2.1.4 Require a marijuana establishment to take corrective actions

14.2.1.5 Order a recall of marijuana or marijuana products

14.2.2 Fines

14.2.2.1 The Commissioner may impose a fine when the public welfare and morals would not be impaired by the imposition of the fine and the payment of the sum of money will achieve the desired disciplinary purposes.

14.2.2.2 Any fine imposed by the Commissioner shall not exceed 10% of the estimated average gross monthly sales of marijuana and marijuana products for the operations of the marijuana establishment within the 12 months immediately preceding the date of the finding of guilt, provided that the amount exceeds $250.

14.2.2.3 In no case shall the Commissioner issue a fine that is less than $250.

14.2.2.4 Each marijuana establishment shall maintain financial records that clearly demonstrate the marijuana establishment's estimated average gross monthly sales of marijuana and marijuana products for the operation of the business within the 12 months preceding the date of the marijuana establishments hearing before the Commissioner and shall, upon demand of the Commissioner, produce the records.

14.2.2.5 Fines issued by the Commissioner shall be paid 30 days from the date of the written decision and order is issued which contains the fine. If a marijuana establishment fails to pay an imposed fine and the matter is not stayed on appeal, the licensee shall be violated under this section for a hearing before the Commissioner, and subject to additional fines, suspension, or cancellation of the license.

14.2.3 License suspension

14.2.3.1 The Commissioner shall suspend a marijuana establishment's license at any time the Commissioner is required to do so by Title 4 of the Delaware Code.

14.2.3.2 The Commissioner may suspend a marijuana establishment's license when the public welfare and morals would not be impaired by the imposition of the suspension and the suspension will achieve the desired disciplinary purposes.

14.2.3.3 The Commissioner may suspend a marijuana establishment's license if the license's violations of Title 4 of the Delaware Code or this regulation are repeated and continuous.

14.2.3.4 The Commissioner may suspend a marijuana establishment's license if the licensee has failed to pay any fine imposed.

14.2.3.5 The Commissioner may suspend any activity that the marijuana establishment license authorizes the licensee to carry out, or all activities that the license authorizes the licensee to carry out.

14.2.3.6 The length of the suspension is at the discretion of the Commissioner.

14.2.3.7 When the license of a marijuana establishment is suspended, the Commissioner, or his designee, shall post conspicuously upon the outer door of the licensed premise a sign stating at minimum the following, "MARIJUANA LICENSE SUSPENDED FOR VIOLATION OF THE DELAWARE MARIJUANA CONTROL ACT". The design of the sign, including the lettering and coloring, must be as designated by the Commissioner. The sign shall remain at all times the property of the Commissioner and shall, remain where so affixed by an officer of the Division until removed by order of the Commissioner. The licensee shall not remove, tamper with, or in any way mutilate the sign, directly or indirectly. Violation of this subsection is cause for the cancellation of the license.

14.2.3.8 When the Commissioner suspends a license, the licensee must not, make any sales, deliveries, or in any manner dispose of the marijuana or marijuana products in the licensee's possession during the period of suspension. In the event that it appears that a sale, delivery, or any disposition of marijuana or marijuana products has been made, the licensee shall be cited to appear before the Commissioner for a hearing. If found guilty, the licensee's license shall be canceled.

14.2.4 License cancellation

14.2.4.1 The Commissioner may cancel a marijuana establishment's license at any time the Commissioner is authorized to do so by Title 4 of the Delaware Code.

14.2.4.2 The Commissioner may cancel a marijuana establishment's license if the licensee has committed violations of Title 4 of the Delaware Code or this regulation which are repeated and continuous, and where the imposition of fines and suspension have not had the desired deterrent effect.

14.2.5 Corrective actions

14.2.5.1 The Commissioner may require a marijuana establishment to take any corrective action necessary and reasonable to prevent continued violations of Title 4 of the Delaware Code or this regulation.

14.2.5.2 The Commissioner may consider the cost of any corrective action in determining a reduction of a fine issued against a marijuana establishment.

14.2.6 Recalls

14.2.6.1 The Commissioner may require a marijuana establishment to recall any marijuana or marijuana products based on evidence that the marijuana or marijuana products:

14.2.6.1.1 Contain an unauthorized pesticide;

14.2.6.1.2 Failed a mandatory test and were not mitigated pursuant to testing protocols;

14.2.6.1.3 Are determined unfit for human use, consumption, or application;

14.2.6.1.4 Are not properly packaged or labeled;

14.2.6.1.5 Are not cultivated or manufactured by a licensed marijuana establishment; or

14.2.6.1.6 Pose a risk to public health and safety.

14.2.6.2 In the event a recall is required, the Commissioner shall:

14.2.6.2.1 Notify the marijuana establishments impacted by the recall;

14.2.6.2.2 Notify the public;

14.2.6.2.3 Lock all marijuana or marijuana products subject to the recall in the seed-to-sale tracking system; and

14.2.6.2.4 Require a marijuana establishment to notify individuals whom may have purchased the marijuana or marijuana products subject to the recall.

14.2.7 Seizure and administrative holds of marijuana or marijuana products

14.2.7.1 Nothing in this regulation prevents the Division from seizing marijuana or marijuana products as permitted by law.

14.2.7.2 The Division may utilize an administrative hold in lieu of seizing marijuana or marijuana products to preserve marijuana and marijuana products during an investigation.

14.2.7.2.1 The Division shall issue a notice to the marijuana establishment of the administrative hold. The notice shall provide a description of the marijuana or marijuana products subject to the administrative hold, the reason for issuing the hold, and the date that the administrative hold

expires. The Division may lift the administrative hold at any time prior to the expiration by informing the marijuana establishment in writing.

14.2.7.2.2 Following the issuance of the notice of administrative hold, the Division shall identify the marijuana or marijuana products subject to the administrative hold in the seed-to-sale tracking system.

14.2.7.2.3 The marijuana establishment must completely and physically segregate the marijuana or marijuana products subject to the administrative hold in a secure location on the licensed premise.

14.2.7.2.4 The marijuana establishment is prohibited from selling, giving away, transferring, transporting, or destroying the marijuana or marijuana products subject to the administrative hold, unless approved by the Division in writing.

14.2.7.2.5 An administrative hold shall not prohibit the marijuana establishment from continuing the cultivation process of marijuana or marijuana products that are subject to an administrative hold.

14.2.7.2.6 An administrative hold shall expire after 45 days unless a new notice of administrative hold is issued by the Division.

14.2.7.2.7 If the marijuana or marijuana products subject to an administrative hold are associated with a violation pending before the Commissioner, the administrative hold shall continue until the conclusion of the hearing and any related appeal.

14.2.7.2.8 A marijuana establishment may petition the Commissioner for a hearing to lift the administrative hold. The Division shall present the reason and justification for the administrative hold. The Commissioner may affirm, revoke or modify the administrative hold.

**15.0 Variances**

15.1 The Commissioner may grant a variance or waiver to this regulation if the Commissioner finds there is no threat to public health or safety and when a person subject to that rule demonstrates that the purpose of the rule can be achieved by other means and strict application of the rule would create a substantial hardship on that person.

15.2 In order to be considered, variances must be submitted in writing in the form and manner set forth by the Commissioner.

15.3 A variance shall not be transferable from person to person, nor from location to location.

15.4 If a variance is granted, the Commissioner shall retain the following information:

15.4.1 A statement of the proposed variance, citing the relevant section of this regulation;

15.4.2 An analysis of how any potential threat to public health or safety will be alternatively addressed by the proposal; and

15.4.3 Any other information the Commissioner deems necessary to render judgment.

**16.0 Consumer Complaints about Marijuana Establishments**

16.1 Consumers may submit complaints about marijuana establishments or products by email to the Commissioner at OMC@delaware.gov or submission of form provided on the Commissioner's website at https://omc.delaware.gov/.

16.2 Notice will be provided that the complaint has been received and the complaint will be investigated.

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**28 DE Reg. 226 (09/01/24)**
**28 DE Reg. 317 (10/01/24)**
**29 DE Reg. 221 (09/01/25)**