216-RICR-60-05-6

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 60 – LABORATORIES AND MEDICAL EXAMINER

SUBCHAPTER 05 – STATE LABORATORY

PART 6 – Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana

6.1 Authority

These regulations are established pursuant to R.I. Gen. Laws §§ 21-28.6-12(f)(10) and 21-28.6-16(f) for the purpose of establishing the minimum standards for licensing analytical laboratories to collect, sample, and analyze medical marijuana products cultivated and/or manufactured by registered compassion centers and licensed cultivators. This is required to ensure the qualifications and competence of personnel and to ensure the adequacy of equipment, facilities, procedures, and quality systems required to characterize cannabinoid identity and content profiles, and test samples of finished medical marijuana products for biological and chemical contaminants. These regulations also establish the form and content of initial and renewal applications for licensing.

6.2 Limitations

The scope of these regulations is limited to authorized activities under the Rhode Island Medical Marijuana Program and does not extend to any acquisition, possession, cultivation, manufacture, delivery, transfer, transportation, or sale for non-medical purposes. See R.I. Gen. Laws §§ 21-28.6-3(15) and 21-28.6-2(5).

The protections and immunities for participation in the Rhode Island Medical Marijuana Program set forth in the Medical Marijuana Act do not apply to any activities beyond the borders of the state of Rhode Island.

6.3 Incorporated Materials

A. These Regulations hereby adopt and incorporate 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 these Regulations.

B. These Regulations hereby adopt and incorporate 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 these Regulations.

C. These Regulations hereby adopt and incorporate 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 these Regulations.

D. These Regulations hereby adopt and incorporate U.S. Department of Agriculture, National Organic Program and National Science and Technology Program 2012b. "2010—2011 Pilot Study Pesticide Residue Testing of Organic Produce" (November 2012), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these Regulations.

6.4 Definitions

A. “Accredited” means to be recognized as conforming to a standard by an accrediting organization.

B. "Act" means the Laboratory Act of R.I. Gen. Laws Chapter 23-16.2, as amended, entitled, "Laboratories."

C. "AHP" means the American Herbal Pharmacopoeia.

D. "Analytical laboratory" means a facility for the biological, microbiological, chemical, and physical examination of medical marijuana and other matrices containing medical marijuana for medicinal purposes.

E. “Analytical reagent grade", "(AR) grade", "ACS reagent grade", and "Reagent grade" mean reagents that conform to the current specifications of the Committee on Analytical Reagents of the American Chemical Society (ACS).

F. "AOAC" means AOAC INTERNATIONAL.

G. “Applicant” means a laboratory applying to the Department to become a licensed analytical laboratory.

H. "Cannabinoid" means any of several compounds produced by cannabis plants including marijuana that have medical and/or psychotropic effects.

I. "Cannabinoid profile" means the percentages of Δ9-tetrahydrocannnabinol (Δ9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) in the total amount of THC in the medical marijuana product as sold. Percentage of other cannabinoids may be reported, but are not required.

J. "Cannabis concentrate" means a marijuana product derived by using solvents or by other means to extract and concentrate cannabinoid compounds. Concentrates are typically in the form of oils, pastes, waxes, or solids.

K. "Cannabis resin", commonly known as “hashish,” “hash,” or “bubble hash,” means a solid medical marijuana product produced by gathering and compressing the cannabinoid-rich trichomes (i.e., kief) of the marijuana plant.

L. "Certified thermometer" means a thermometer that has documentation from the manufacturer that it has been calibrated by NIST.

M. "Class ‘A’ glassware" means glassware satisfying the applicable requirements for Class “A” glassware established by NIST.

N. "Change in owner" means:

1. In the case of an analytical laboratory that is a partnership, the removal, addition, or substitution of a partner which results in a new partner acquiring a controlling interest in such partnership;

2. In the case of an analytical laboratory which is an unincorporated solo proprietorship, the transfer of the title and property to another person;

3. In the case of an analytical laboratory which is a corporation:

    a. A sale, lease, exchange, or other disposition of all, or substantially all, of the property and assets of the corporation; or

    b. A merger of the corporation into another corporation; or

    c. The consolidation of two or more corporations, resulting in the creation of a new corporation; or

    d. In the case of an analytical laboratory which is a business corporation, any transfer of corporate stock which results in a new person acquiring a controlling interest in such corporation; or

    e. In the case of an analytical laboratory which is a non-business corporation, any change in membership which results in a new person acquiring a controlling vote in such corporation.

O. "Compassion center" means a not-for-profit corporation subject to the provisions of R.I. Gen. Laws Chapter 7-6, and registered under R.I. Gen. Laws § 21-28.6-12 that acquires, possesses, cultivates, manufactures, delivers, transfers, transports, supplies or dispenses marijuana, and/or related supplies and educational materials, to patient cardholders and/or their registered caregiver cardholder and authorized purchaser.

P. "Compliance analysis" or "Compliance testing" means the analysis of a sample that is required by law or regulation.

Q. "Data quality objectives" or "DQO" means performance and acceptance criteria developed to clarify study objectives, define the appropriate type of data, and specify tolerable levels of acceptable data.

R. "Department of Business Regulation", or “DBR,” means the Rhode Island Department of Business Regulation or its successor agency.

S. "Department" or "RIDOH" means the Rhode Island Department of Health.

T. "Detection limit" means the minimum concentration of a substance that can be measured and reported with 99% confidence that the analyte concentration is greater than zero and is determined from analysis of a sample in a matrix containing the analyte.

U. "Director" means the Director of the Rhode Island Department of Health.

V. "Dried useable marijuana" means the dried leaves and flowers of the marijuana plant as defined by regulations promulgated by the department of health.

W. "Duplicate samples" means two samples collected from and representative of the same material that are carried through all steps of the sample accessioning, preparation and analytical procedures in an identical manner.

X. "Edible marijuana-infused products" or "Edibles" means a medical marijuana-infused product that is to be consumed by eating or drinking.

Y. "Emergency sampling and handling" means upon direction by the Department or DBR, samples of medical marijuana products must be collected, analyzed, and reported as a priority.

Z. "Equivalent amount" means the documented weighed and measured portion of usable marijuana components used in the manufacturing process to determine the final concentration of cannabinoids in the finished edible and infused medical marijuana products.

AA. "FDA" means the United States Food and Drug Administration.

BB. "Finished medical marijuana" means usable plant material, cannabis resin, cannabis concentrate, or marijuana-infused product (MIP). Anything not falling within this definition may be referred to as “unfinished” herein.

CC. "Finished plant material" means usable marijuana that has been trimmed and dried. Trimming includes removing the leaves subtending the buds as well as any dead leaves or stems.

DD. "Flowering" means the gametophytic or reproductive state of marijuana in which the plant produces flowers, trichomes, and cannabinoids characteristic of marijuana. This stage of growth is determined by visual buds or flower or by proxy of the plant receiving less than eighteen (18) hours of light in a twenty-four (24) hour period.

EE. "Laboratory fortified blank" means a laboratory reagent blank that includes the target analytes for which the analytical method is designed to detect and quantify in medical marijuana samples.

FF. "Laboratory fortified sample" means a medical marijuana sample that includes the target analytes for which the analytical method is designed to detect and quantify.

GG. "Laboratory reagent blank" means a sample composed of a clean matrix and analyzed as a medical marijuana product sample. It contains only the reagents used in the preparation of the sample and is analyzed and treated in the manner as the medical marijuana samples.

HH. "Licensed" means the determination by the Department of Health that an analytical laboratory is capable of performing specific tests or analyses of medical marijuana samples in accordance with the requirements of these Regulations.

II. "Licensed cultivator" means a person as identified in R.I. Gen. Laws § 21-28.6-16, who has been licensed by the department of business regulation to cultivate marijuana pursuant to R.I. Gen. Laws § 21-28.6-16, and may also refer to their agents or card holders as the context may require.

JJ. "Marijuana" means all parts of the plant of any Cannabis species whether growing or not; the seeds thereof; and resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature

stalks, except the resin extracted therefrom, fiber, oil, or cake or the sterilized seed of the plant which is incapable of germination.

KK. "Marijuana-Infused product" or "MIP" means a product infused with marijuana that is intended for use or consumption, including but not limited to edible products, ointments, aerosols, oils, and tinctures. These products, when created or sold by a compassion center, shall not be considered a food.

LL. "Mature marijuana plant" means a marijuana plant that has flowers or buds that are readily observable by an unaided visual examination.

MM. “Medical Marijuana Act” refers to R.I. Gen. Laws Chapter 21-28.6 entitled “The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act,” as amended, including amendment by the 2016 Public Laws, Chapter 142 (Budget Article 14).

NN. “Medical marijuana program tracking system” shall refer to any system(s) designated by DBR and RIDOH designed and used to record and track all “seed to sale” activities and transactions with unique identifiers. The Medical Marijuana Program Tracking System may also be used for registration, licensing applications, renewals, change of information, and communications, as well as to record and/or report any other additional information directed by DBR or RIDOH.

OO. "Medical use" means the acquisition, possession, cultivation, manufacture, use, delivery, transfer, or transportation of marijuana or paraphernalia relating to the consumption of marijuana to alleviate a patient cardholder's debilitating medical condition or symptoms associated with the medical condition.

PP. "NIST" means National Institute of Standards and Technology.

QQ. "Persons" means any individual, firm, partnership, corporation, company, association, or joint stock ownership.

RR. "Production batch" means a lot or a batch of finished medical marijuana product of plant material, cannabis resin, cannabis concentrate, or MIP produced at the same time, using the same methods, equipment, and ingredients. The medical marijuana producer of finished products must assign and record a unique, sequential alphanumeric identifier to each production batch for product tracking, labeling, and recalls.

SS. "Proficiency testing sample" or "PT sample" means a subsample of a matrix containing analytes of a concentration unknown to the laboratory that is used to evaluate the performance of its analytical systems. Proficiency testing samples must be obtained from a provider that is accredited by an accreditation body approved by the director of RIDOH.

TT. "Propagation" means the reproduction of marijuana plants by seeds, cuttings, or grafting.

UU. "Quality assurance" or "QA" means the integrated system of operations and measurements performed to assure that data meets defined standards of quality within a stated level of confidence.

VV. "Quality assurance plan" or "QAP" means the laboratory's documented integrated system of operations and measurements performed to assure that data meets defined standards of quality within a stated level of confidence.

WW. "Quality control" or "QC" means the practice of standardized operations or measurements that determine or predict aspects of data quality.

XX. "Registry identification card" means a document issued by the department of business regulation that identifies a person as a testing agent for one or more registered compassion centers and/or licensed cultivators.

YY. "Replicate" means one of at least three portions of a sample prepared and analyzed together to determine the range of cannabinoid potency in a lot.

ZZ. "Residual solvent" means a volatile organic chemical used in the manufacture of a medical marijuana product and that is not completely removed by practical manufacturing techniques.

AAA. "Sample duplicate" means two portions of collected sample prepared and analyzed in the same batch by the analytical laboratory used to determine analytical precision.

BBB. "Seed to sale" shall refer to all medical marijuana program regulated activities and transactions from point of origin to the point of sale. Seed to sale activities and transactions include but are not limited to: all cultivation, harvest, processing, manufacturing, and packaging and labeling; all purchases, acquisitions or third party supply of marijuana; all sales and dispensing transactions, any other transfers of marijuana as permitted by the Medical Marijuana Act and all applicable regulations promulgated thereto; any instances of destruction of marijuana; and testing compliance tracking.

CCC. "Standard methods" means published by the Standard Methods for the Examination of Water and Wastewater, American Public Health Association (APHA).

DDD. "Sporophytic state of the marijuana plant" means the vegetative stage of asexual reproduction in plants during which plants do not produce resin or flowers and

are bulking up to a desired production size for flowering (more than 18 hours photogenic light).

EEE. "Testing agent" means an employee of an approved analytical laboratory who performs sampling and / or analysis of medical marijuana products in accordance with these regulations.

FFF. "These regulations" means all parts of the Rules and Regulations for Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana [216-RICR-60-05-6].

GGG. "Tincture" means an extract, typically in ethanol, of usable marijuana. Marijuana tinctures sometimes are made with glycerin or other alternatives to ethanol.

HHH. "Trichome" means a cannabinoid-producing glandular structure that grows on the plant surface of marijuana plants, particularly on the buds of the female plant.

III. "Upper limit" means the maximum allowable concentration of contaminant in the medical marijuana product.

JJJ. "Usable marijuana" means dried leaves and flowers of the marijuana plant, and any mixture or preparation thereof, but does not include the seeds, stalks, and roots of the plant.

KKK. "USP" means United States Pharmacopeia.

LLL. "Water activity" means the unbound water in plant or food products that can support the growth of bacteria, yeasts and molds (fungi). Water activity represents the ratio of the water vapor pressure of the product to the water vapor pressure of pure water under the same conditions and it is expressed as a fraction.

MMM. "Wet marijuana" means the harvested leaves and flowers of the marijuana plant before they have reached a dry useable state, as defined by regulations promulgated by the departments of health and business regulation.

NNN. "WHO" or the "World Health Organization" means an agency of the United Nations, established in 1948, concerned with improving the health of the world's people and preventing or controlling communicable diseases on a worldwide basis through various technical projects and programs.

6.5 Medical Marijuana Program Tracking System

A. Upon direction by RIDOH, each analytical laboratory licensed under the provisions of these regulations shall be required to utilize the state approved

Medical Marijuana Program Tracking System to document and monitor compliance with the Medical Marijuana Act, and these regulations and may be required to pay costs associated with use of the Medical Marijuana Program Tracking System which may be assessed on an annual, monthly, per use, or per volume basis and payable to the state or to its approved vendor.

B. In accordance with the Uniform Electronic Transactions Act (UETA), R.I. Gen. Laws Chapter 42-127.1 RIDOH may determine whether, and the extent to which, it will accept electronic records, documents, notifications, and signatures from other persons or entities where these regulations refer to written records, documents, notifications, and signatures.

C. Wherever these regulations have recordkeeping and reporting requirements, such data and information must be recorded and reported through the Medical Marijuana Program Tracking System wherever said System is configured for such recording and reporting, in addition to any other means/mechanisms of recording and reporting required by RIDOH. RIDOH will provide further guidance on use of the Medical Marijuana Program Tracking System, when it is mandatory or encouraged to be used as a substitute for or supplement to any other specifically mentioned means/mechanisms in these regulations, and timing for system utilization.

D. If a laboratory is licensed prior to the implementation of the Marijuana Program Tracking System, RIDOH will advise the laboratory of acceptable alternative tracking systems and protocols. In such a case, any references to the Medical Marijuana Program Tracking System in these regulations shall be deemed to include the acceptable alternatives.

6.6 Application and Licensing Process Details

The analytical laboratory must fulfill the following general requirements to apply for and renew a license for sampling and testing medical marijuana. Unless otherwise specified, all requirements of these regulations apply to the analytical laboratory.

6.6.1 General Requirements

A. Submit application for a license on forms provided by the RIDOH for initial licensing and for license renewal.

B. Include information as the RIDOH requires which may include affirmative evidence of ability to comply with the provisions of the Medical Marijuana Act and these Regulations.

C. RIDOH will evaluate applicants based upon the information provided by applicants on the application forms/submissions and otherwise obtained during the application process.

D. Only applications that RIDOH has determined to be complete shall be eligible for review. An applicant who submits an incomplete application shall receive written notification from RIDOH regarding the specific deficiencies and shall be allowed to resubmit additional material to address these deficiencies within 30 days.

E. Upon notification of an approval of an application from RIDOH, the approved applicant must take reasonable and documented efforts to complete the prerequisites to the issuance of a license. If such efforts take longer than nine (9) months, the approved applicant must show good cause to RIDOH why additional time should be granted and the application approval should not be rescinded.

6.6.2 Submit Application to RIDOH- Articles of Incorporation, Business Plan, Zoning Compliance, Tax Affidavit, Security Plan, and Application Fee

A. The applicant's legal and any d/b/a name(s), certificate of incorporation under R.I. Gen. Laws § 7-6-36 or certificate of authority under R.I. Gen. Laws § 7-6-70, articles of incorporation and by-laws, and, if applicable, documentation of recognition as a tax-exempt organization by the US Internal Revenue Service.

B. A business plan, including scope of activities, budget and resource narratives, and timeline for initiating operations.

C. The proposed physical location of the analytical laboratory (by plat and lot number and mailing address), if a precise location has been determined. If a precise physical location has not been determined, a description of the general location(s) where it may be sited, if approved, and the expected schedule for purchasing or leasing said location(s). Regarding the proposed physical location(s), the applicant must submit:

1. evidence of compliance or preliminary determination of compatibility of the location(s) with the local zoning laws;

2. a draft diagram of the proposed facilities, including where within the facility the medical marijuana will be received, held for processing, prepared for testing, and analyzed, and where security alarms and cameras and surveillance recording storage will be located, and showing the location of the facility relative to streets and other public areas;

3. a description of objective parameters (such as distances from streets and public areas) and/or proposed measures (such as black-out window

shades) that ensure that marijuana at the premises must not be visible from the street or other public areas; and,

4. evidence of either ownership of property or agreement by owner of property to allow the operation of an analytical laboratory on the property, if property has already been purchased or leased at the time of the application.

D. The legal name, current address, and date of birth of each principal officer, director, or owner of the analytical laboratory.

E. A list of all persons or entities (legal names and current addresses) having direct or indirect authority over the management or policies of the analytical laboratory.

F. If an analytical laboratory will have a management agreement in place, it must also include a copy of the management agreement or management agreement proposal and a list of persons who have any ownership interest or operational control over the management company.

G. A list of all persons or business entities (legal names and current addresses) having any ownership interest in the applicant entity, whether direct or indirect.

H. If the analytical laboratory premises and/or other operational assets will be owned or leased by a person or entity other than the applicant, the legal name and current address of such person or entity and a list of all persons or entities (legal names and current addresses) having any ownership interest in such entity, whether direct or indirect.

I. The legal names and current addresses of all creditors holding a security interest in the premises and/or other assets to be used in the analytical laboratory operations, if any.

J. Tax Affidavit in accordance with R.I. Gen. Laws Chapter 5-76.

K. All other information required by RIDOH as described in the application form.

L. Each application must include the non-refundable application fee as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory, and Administrative Services Provided by the Department of Health (Part 10-5-2 of this Title).

6.6.3 RIDOH and DBR Review

RIDOH and DBR will conduct a preliminary inspection of the proposed facility design and layout.

6.6.4 Preliminary Application Approval

If RIDOH receives all required information and the information meets all applicable requirements, the application will receive preliminary approval.

6.6.5 Building Process

A. If an applicant is notified that its application has been preliminarily approved by RIDOH, it must provide the following before being issued a license to operate:

1. all updates to previously submitted application information;

2. a sufficient description of the final physical location of the analytical laboratory (by plat and lot number and mailing address);

3. evidence of complete compliance of the facility with the local zoning laws, including any conditions of approval thereof, in the form of a letter from an authorized zoning official of the municipality and certification by an authorized officer of the applicant as to compliance with any other applicable local ordinances;

4. a current Certificate of Occupancy (or equivalent document) to demonstrate compliance with the relevant provisions of R.I. Gen. Laws Chapters 23-28.1 and 23-27.3 [Fire Safety Code and State Building Code, respectively] for each physical address to be utilized as an analytical laboratory.;

5. evidence of either ownership of property or agreement by owner of property to allow the operation of an analytical laboratory on the property;

6. a final diagram of the facilities, including where within the facilities the medical marijuana will be stored and analyzed, and where security alarms and cameras and surveillance recording storage will be located, and showing the location of the facilities relative to streets and other public areas;

7. evidence of divestiture of prohibited material financial interest and control as follows:

    a. An analytical laboratory and “key persons” thereof may not have any “material financial interest or control” in a compassion center, a cultivator, or a licensed cooperative cultivation or vice versa.

    b. "Material financial interest or control” shall mean: any ownership interest, regardless of the size of the holding, and including any

ownership interest through a subsidiary or affiliate; trusteeship, mortgage, guarantor, endorser or surety relationship, or loan relationship, except that loan relationship for the purposes of this definition shall exclude accounts payable and accounts receivable on account of a medical marijuana purchase order; any other beneficial financial interest such that the holder bears the risk of loss (other than as an insurer) or has an opportunity to gain profit from the operation or sale of the regulated medical marijuana business; or, operational control, including but not limited to interlocking directors or officers or through a management agreement.

c. "Key persons" shall mean directors, officers, and any persons with managing or operational control.

d. If an analytical laboratory application is approved and any prohibited material, financial interest or control has been identified by DBR or is otherwise known to the analytical laboratory applicant, such interest or control must be divested prior to issuance of the analytical laboratory license. The plan of divestiture must be filed with DBR.

e. The duty to divest prohibited material financial interests and control is a continuing obligation of licensing.

8. evidence that all directors, managers, officers, agents and employees of the analytical laboratory have applied for a Registry Identification Card(s) from DBR (under the rules and regulations related to the Medical Marijuana Program Administered by the Department of Business Regulation (230-RICR-80-05-1.3 and 1.6) which includes a background check;

a. Such persons must apply for registry identification card(s) to document their status as a testing agent for a licensed analytical laboratory.

b. Such persons maybe hired, appointed, or retained prior to receiving a Registry Identification Card(s), but may not begin engagement in medical marijuana testing, sampling or other medical marijuana laboratory activities until receipt of the card.

B. The applicant must submit the laboratory quality assurance plan and procedures manual to RIDOH as described in § 6.11 of this Part.

6.6.6 Final Licensing Process

A. Submit documentation of approval of occupancy from the State Fire Marshall to RIDOH.

B. Submit a copy of all Registry Identification Card(s) from DBR to RIDOH. Each laboratory must maintain a current list of testing agent cardholders employed by the laboratory.

C. Pay the annual license fees as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory, and Administrative Services Provided by the Department of Health (Part 10-5-2 of this Title).

D. The Department shall issue a license no less than 30 days after the applicant meets the licensing requirements of these regulations.

E. Once the license has been issued by RIDOH, the analytical laboratory must take reasonable and documented efforts to launch analytical laboratory activities, which for purposes of this paragraph shall mean actual medical marijuana sampling and analysis and/or other medical marijuana activities requiring an analytical laboratory license pursuant to these regulations. If such efforts take longer than one (1) year, the analytical laboratory must show good cause to RIDOH why the license should not be revoked for non-use.

F. The applicant must contact RIDOH to coordinate a final laboratory inspection. RIDOH, DBR and/or the Rhode Island State Police will visit the analytical laboratory to inspect the facility security and make any recommendations regarding the security of the facility and its personnel within ten (10) business days prior to the initial opening of the analytical laboratory. RIDOH may also conduct an inspection at an earlier time, if necessary, in addition to a final laboratory inspection.

6.7 Licensing

6.7.1 General Information

A. Licenses will not be issued to an analytical laboratory prior to an inspection and correction of any deficiencies in a manner acceptable to the RIDOH.

B. Analytical laboratories may receive samples from another laboratory in this state for examination provided the laboratory sending the samples is licensed in this state pursuant to these rules and regulations.

C. A license will be issued only for the premises and persons named in the application and will not be transferable or assignable.

D. The license issued will be the property of the state and loaned to the laboratory and must be kept posted in a conspicuous place on the premises. Said license, unless sooner suspended or revoked, shall expire by limitation on the 31st day of December, of every year following the date of licensing and shall be renewed annually.

E. The license issued to an analytical laboratory shall clearly identify the name of the laboratory, the license number, the name of the laboratory director, the issue date and expiration date. The license will include a list of the analytes and methods for each test category the laboratory is approved. Test categories approved for the analysis of medical marijuana plant materials will be listed separately from those approved for extracts, concentrates and resins.

F. Test categories and descriptions are as follows:

1. Medical marijuana finished plant material:

    a. Cannabinoid Potency – Quantitative analysis including the percentage of D 9 -tetrahydrocannnabinol (D 9 -THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) of the total amount of THC in a medical marijuana product. Amounts of other cannabinoids may be reported, but are not required.

    b. Microbiological - total viable aerobic bacteria, total coliforms, bile-tolerant gram-negative bacteria, pathogenic E. coli, Salmonella, yeast, and mold.

    c. Water Activity – total water activity.

    d. Pesticides – Residues of pesticides and growth regulators listed in § 6.21(E)(1)(a) of this Part.

    e. Metals – Arsenic, Cadmium, Lead, Mercury.

2. Medical marijuana extracts, resins, concentrates as-is or as components of medical marijuana infused products:

    a. Cannabinoid Potency – Quantitative analysis including the percentage of D 9 -tetrahydrocannnabinol (D 9 -THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) of the total amount of THC in a medical marijuana product. Amounts of other cannabinoids may be reported, but are not required.

b. Solvents – Listed in § 6.21(H)(3) of this Part.

c. Pesticides – Residues of pesticides and growth regulators listed in § 6.21(E)(1)(a) of this Part.

d. Metals - § 6.21(D)(2)(a) of this Part.

G. The license will be void and returned to RIDOH if the analytical laboratory discontinues its operation, unless the discontinuance is on a temporary basis approved by RIDOH.

6.7.2 Post-Licensing Change Notification

A. The analytical laboratory shall provide RIDOH with a written notice of any change described below at least thirty (30) calendar days prior to the proposed effective date of the change:

1. change in ownership of the analytical laboratory as defined in § 6.4(N) of this Part;

2. change in the laboratory director;

3. change in the quality assurance officer;

4. merger, dissolution, or entity conversion;

5. entering a management agreement, changing management companies, and/or material changes to an existing management agreement;

6. changes in the approved premises location for the laboratory analysis of medical marijuana;

7 change to approved premises floor plan;

8. proposed premises expansion; or,

9. discontinuation of or failure to launch analytical laboratory activities.

B. Unless the analytical laboratory provides timely notification of the above changes and receives prior RIDOH approval or waiver of the requirement of prior notice and approval (for example a non-material change in ownership or emergency as determined by RIDOH), the license shall be void and returned to RIDOH.

C. The analytical laboratory must follow the process for a new application, including a new application fee, for:

1. Any proposed change of ownership;

2. Any change to a management agreement that will effect a change of majority control and/or decision-making authority with respect to the operation of the analytical laboratory; and

3. Any proposed change in an approved premises location for the laboratory analysis of medical marijuana.

D. For updates in information other than the categories requiring thirty (30) calendar days prior notice pursuant to § 6.7.2(A) of this Part, the analytical laboratory has a continuing obligation to update, amend and/or correct any information requested and/or submitted in the application process within ten (10) business days after any change in the information submitted and/or any material change in circumstances related to the application. This includes timely notification and divestiture if a prohibited interest.

E. If the analytical laboratory proposes to alter or expand the final floor plan previously submitted and approved, the analytical laboratory must first submit a renovation plan for RIDOH approval at least 60 (sixty) calendar days prior to commencement of construction. The renovation plan must specifically address quality control procedures for the protection of medical marijuana samples and medical marijuana product samples from any contamination during the construction process and further address any other criteria RIDOH requires.

6.7.3 Annual License Renewal

A. Analytical laboratory licenses shall be issued for one year terms.

B. Annual license renewal applications shall be submitted on such forms and include such information as prescribed by RIDOH.

6.7.4 Denial, Suspension, or Revocation of License

A. The Department may deny, revoke, or suspend the license of any analytical laboratory for engaging in conduct that includes but is not limited to:

1. failure to observe any term of licensing;

2. failure to observe any order made under authority of the Medical Marijuana Act or under the statutory authority vested in the Department;

3. engaging in, aiding, abetting, causing, or permitting any action prohibited under the Medical Marijuana Act;

4. failure to comply with any regulatory requirement stated herein and any other applicable state regulation or statute;

5. making false or deceptive representation on any application for license or renewal thereof;

6. failure to maintain professional and competent standards of practice;

7. making false or deceptive representation of any testing results and reports thereof; or,

8. engaging in false or deceptive advertising.

B. Lists of deficiencies noted in inspections and investigations conducted by the RIDOH shall be maintained on file in the RIDOH and shall be considered by the RIDOH in rendering determinations to deny, suspend, or revoke the license of an analytical laboratory.

C. Whenever action shall be proposed to deny, suspend, or revoke the license or take another disciplinary action, the RIDOH shall notify the facility by certified mail setting forth reasons for the proposed action, and the applicant or licensed laboratory shall be given an opportunity for a prompt and fair hearing in accordance with R.I. Gen. Laws § 23-1-22 and these Regulations.

D. If the RIDOH finds that public health, safety and welfare imperatively requires emergency action and incorporates a finding to that effect in its order, the RIDOH may order summary suspension of licenses pending proceedings for revocation or other action in accordance with R.I. Gen. Laws §§ 23-1-20 and 42-35-14(c).

6.8 Inspections

A. After the analytical laboratory license is issued, the analytical laboratory shall notify RIDOH when it commences operations. RIDOH may conduct a post-licensing inspection upon this commencement of operations, including but not limited to inspection for compliance of medical marijuana product sampling, chain of custody and testing requirements set forth in these regulations.

B. The Director or authorized agent(s) shall at all times have authority to enter upon all parts of the premises on which any medical marijuana plant or product analysis is conducted and of the premises appurtenant thereto, as well as the premises on which finished medical marijuana plant or products samples are collected by employees of the analytical laboratory testing. The purpose of these visits will be to observe and evaluate the sample collection and chain of custody procedures and/or for determining compliance with the provisions of the Medical Marijuana Act and these Regulations.

C. Each medical marijuana analytical laboratory shall be provided a written report by the Department of all deficiencies recorded because of an inspection or investigation within sixty (60) days of such inspection or investigation.

D. The medical marijuana analytical laboratory shall provide a plan of corrective action, including expected completion dates for all deficiencies listed on such report within thirty (30) days of receipt.

E. At the discretion of the Director, a follow-up inspection may be conducted to assure that all deficiencies have been corrected.

6.9 Laboratory Governing Body, Management, and Personnel

6.9.1 Governing Body

A. Each laboratory must have a governing body or equivalent legal authority ultimately responsible for:

1. the management and control of the operation;

2. the assurance of the quality of services;

3. the compliance with all state and local laws and regulations; and

4. compliance with other relevant health and safety requirements, including these Regulations.

6.9.2 Management

A. Each laboratory shall have a laboratory director who must be responsible for the day-to-day management and operation of the laboratory and to ensure the achievement and maintenance of quality standards of practice. The laboratory director must meet the following minimum qualifications:

1. be a person of good moral character; and,

2. possess a doctorate in the chemical or biological sciences from a college or university accredited by a national or regional certifying authority and a minimum of two (2) years analytical laboratory experience, or possess a master's degree in the chemical or biological sciences and a minimum of four (4) years of analytical laboratory experience, or possess a bachelor’s degree in the chemical or biological sciences and a minimum of five (5) years of analytical laboratory experience.

B. The director of each laboratory or his/her designee, must be responsible for the following:

1. to be present on the premises of the laboratory during the hours of operation to ensure adequate and appropriate supervision of laboratory activities;

2. to ensure the accurate performance of all tests in the laboratory including the submission of appropriate reports on all tests;

3. to ensure the supervision of all personnel in the laboratory and for hiring adequately trained personnel commensurate with the workload;

4. to be available during the hours of operation for personal or telephone consultation with personnel;

5. to notify the RIDOH within thirty (30) days of any change in laboratory services or supervisory personnel;

6. to establish and adhere to written policies and procedures for a comprehensive quality assurance program; and

7. such other activity as may be deemed appropriate.

C. In the event the director of the laboratory is absent for a continuous period longer than one-month duration, the laboratory must not operate unless a person who meets the qualifications of § 6.9.2(B) of this Part is in attendance.

D. The laboratory director must designate a qualified quality assurance officer who is responsible for the laboratory's quality assurance plan and its implementation. This individual may be an outside consultant or the laboratory director.

E. The quality assurance officer must have earned at least a bachelor's degree in a chemical or biological science and two years of related laboratory experience. The quality assurance officer qualifications may be met if the person has previous laboratory quality assurance experience acceptable to the RIDOH in a licensed, certified, or accredited laboratory, or possesses other qualifications acceptable to the RIDOH.

F. The quality assurance officer must be responsible for the oversight of QC data, including establishing acceptance criteria and documenting/monitoring corrective action; where staffing allows, be independent of the technical areas for which he/she has QA oversight; have general knowledge of the methodologies for which data review is performed; have oversight of the laboratory's quality assurance system and conduct or arrange for annual internal audits of the technical operation and report findings to the laboratory director.

6.9.3 Personnel

A. Each laboratory must 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.

B. Each laboratory must establish a job description for each classification of position, clearly delineating qualifications, duties, and responsibilities inherent in each position.

C. Each laboratory must maintain personnel records for each employee which contain no less than current background and training documentation pertaining to qualifications; orientation procedures, including an initial demonstration of capability for each method and/or instrument the analyst will be performing and/or operating; evidence of periodic evaluation of work performance; and, such other training records as may be deemed appropriate.

D. Each laboratory must train personnel initially and annually thereafter on professional conduct, ethics, and state laws regarding medical marijuana.

E. Each laboratory must train personnel initially and annually thereafter on the use of the Medical Marijuana Program Tracking System and any other tracking systems used by the laboratory.

6.10 Record Keeping

A. Each laboratory must maintain appropriate records and reports, which must be available for inspection by authorized representatives of the RIDOH. Create, control, and maintain records of raw data, chain-of-custody records, calculations, quality control data, and other essential documentation. Complete all records with signatures, units of measurement, and documentation sufficient for verification of results. Retain all records in such a manner as to permit prompt retrieval. Records must include:

1. records of the operation and maintenance of all laboratory equipment;

2. records of all sample collection, preparation, and analysis;

3. records of control values, standard values, calibration curves and calculations of standard deviations; and

4. reports of proficiency testing programs and of such other records as may be deemed necessary.

B. Each laboratory must maintain the results of all testing including correspondence related to reported results and compliance issues for no less than five (5) years. These records must be available for inspection by the RIDOH, upon request and

maintained at the analytical laboratory's expense in a form and location acceptable to the RIDOH for at least two years after closure.

6.11 Quality Assurance and Quality Control Programs

A. The laboratory must have a quality assurance 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 plan annually. The analytical laboratory must follow all applicable quality control activities described in its quality assurance plan as approved by the RIDOH. Analytical laboratories must review their quality assurance plan annually and provide a copy of the updated quality assurance plan to the RIDOH with the annual renewal application.

B. Each laboratory must have clearly established internal and external quality controls to ensure high standards of performance and reliability of test results. These quality controls must consider such factors as 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.

C. The laboratory must perform all analyses using methods that are currently approved by the RIDOH, as described in § 6.21 of this Part.

D. The laboratory's quality assurance plan must be accessible to all personnel in the laboratory. It must include, but not be limited to:

1. laboratory sampling plan for collecting representative samples of finished medical marijuana products;

2. laboratory sample handling procedures;

3. emergency sampling and handling plan;

4. laboratory glassware, plastic ware and equipment washing and sterilizing procedures;

5. instrument calibration procedures;

6. a list of detailed analytical procedures or analytical references;

7. data reduction, validation, and reporting procedures including non-compliance action plan;

8. types and frequency of internal audit samples (quality control samples) and external audit samples (proficiency testing samples);

9. internal audit procedures and frequency;

10. preventative maintenance procedures and schedules;

11. procedures for determining accuracy and precision and method detection limits of all analytes and specified frequency;

12. control limits and corrective action policies;

13. laboratory organization, staff, and responsibilities;

14. procedures for laboratory and managerial data review;

15. detection limits (DL) for cannabinoids, and contaminant analytes specified in these regulations must be determined by DL 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 these regulations. If the laboratory cannot meet a DL that is less than half of the Upper Limit for an analyte, a request for a variance must be submitted;

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

6.12 Proficiency Testing and Demonstration of Capability

A. The quality assurance plan must include standard procedure for determining the capability of its analysts before they can begin conducting quantitative analysis of medical marijuana products.

B. RIDOH must be notified when significant changes are made to the standard analytical procedure such as changes to extraction technique or the instrumentation used.

C. Each analyst is required to perform initial demonstration of capability prior to implementing routine analyses.

D. Each laboratory must participate in a proficiency testing program approved by the RIDOH for each analyte (or group of analytes), matrix and method for which the laboratory is certified or is requesting certification. Proficiency testing samples must be procured from a proficiency testing provider approved by the RIDOH. RIDOH may require that the proficiency testing program include “round robin”

proficiency testing whereby samples from the same batch are tested by more than one licensed analytical laboratory for comparison of results.

E. If proficiency test samples are not commercially available, analytical laboratories 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:

1. the source of the sample,

2. the matrix type,

3. preparation procedure,

4. testing procedure,

5. target analytes in the sample,

6. how the analyte concentration was determined,

7. control limits and how they were determined, and

8. shelf life and expiration testing.

F. The laboratory must participate in a PT sample annually for each analyte, matrix and method and receive an acceptable evaluation for each of the following:

1. Plants – potency, metals, water activity, pesticides, aerobic plate count bacteria, bile-tolerant gram negative bacteria, pathogenic E. coli, Salmonella, mold, and yeast.

2. Extracts, resins, and concentrates – potency, solvents, and pesticides.

G. Proficiency test results must be submitted by the accredited provider directly to the RIDOH licensing office by October 31 of each year. Analytical laboratories must designate RIDOH as a recipient of the provider's proficiency test results report. Analytical laboratories must not communicate or receive proficiency test results to or from other analytical laboratories before the accredited provider makes them available.

H. When a laboratory 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 PT study for the failed analyte. Documentation of the investigation and corrective action must be maintained and a copy provided to the RIDOH before the next proficiency testing study.

I. Failure to complete PT studies annually or failure to obtain an acceptable result in a PT study will result in loss of licensing for the analyte until two (2) consecutive PT studies resulting in acceptable evaluations have been completed. There must be an interval of at least thirty (30) days between the two studies.

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

K. Laboratories must not send a PT sample, or a portion thereof, to another laboratory for any analysis for which it is certified or seeks certification.

L. A laboratory must not knowingly receive any PT sample, or a portion thereof, from another laboratory for any analysis for which the sending laboratory is licensed or seeks licensing.

M. Laboratory management or staff must not communicate with any individual at another laboratory concerning a PT sample or attempt to obtain the assigned value from their PT provider.

N. All raw data obtained in analyzing PT samples must be retained and be available for review for a minimum of five (5) years.

6.13 Procedure Manual

A. Each analytical laboratory must have available, always, in the immediate working areas of personnel engaged in conducting analytical laboratory sample collection, sample accessioning and testing, a procedure manual which includes a detailed compilation of all automated and manual methods and procedures for sample collection, chain-of-custody, and analytical testing which is performed by the laboratory and for which it is licensed. Such manuals must:

1. be written in a uniformly consistent format;

2. specify the approved method employed;

3. describe the quality control activities pertinent to the method;

4. contain information concerning preparation and storage of media, reagents, control and calibration procedures and pertinent literature references;

5. describe the laboratory's technical procedures for the collection, transporting, processing and examination of samples;

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,

7. be approved, signed, and dated by the current laboratory supervisor/director and the QA Officer. Changes in procedures must be approved, signed, and dated by the current supervisor/director and QA Officer.

6.14 Facility, Equipment & Supplies

6.14.1 Facility

A. Each analytical laboratory must:

1. be housed in well lighted, sanitary, vented quarters equipped with hot and cold running water, and toilet facilities and contain ample space to process and examine the samples commensurate with the total workload;

2. be in distinct and separate locations from living quarters unless provisions exist for separate entrances, and plumbing fixtures;

3. have ample workbench space, have sufficient water, gas, suction, electrical outlets, and sinks;

4. have adequate and proper storage space for all chemicals including explosive, flammable, corrosive, and caustic materials;

5. have flooring composed of non-porous material in laboratory areas where acids, caustics, and solvents are used;

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

7. have adequate electrical supply; and

8. have adequate refrigeration for samples, standards, and reagents used in testing.

6.14.2 Equipment and Supplies

A. The laboratory must possess suitable equipment required for licensing that must meet the requirements of the methods. All instruments must be physically located on site.

B. The laboratory must have sufficient glassware and plastic labware necessary for the analyses. Glassware must be borosilicate glass or other corrosion-resistant glass. It must be free of cracks and chips. Markings and etchings must be legible. Volumetric flasks, pipettes, and other glassware used for volumetric analysis must be class “A”.

C. The laboratory must have sufficient facilities to wash and sterilize glassware, labware, and other containers used in the analysis.

D. All precision equipment and instruments (e.g. pipettors, pH meters, conductivity meters) must be calibrated and checked for accuracy at regular intervals as required by the method and the laboratory’s quality assurance policies. Documentation of calibration and accuracy checks must be maintained. Records of service by a qualified instrument service organization must be maintained.

E. 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 must 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 must be recalibrated every five (5) years or immediately if nicked or corroded. Non-reference weights may be used but must be calibrated every six (6) months against ASTM type 1, 2 or 3 weights.

F. All balances must be calibrated annually by a professional balance service. Certificates of calibration must be maintained at the laboratory.

G. All incubators, refrigerators, ovens, autoclave or sterilizers and water baths must contain calibrated thermometers. The laboratory 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 date of accuracy check and the correction factor (may be zero). There must be no separation in the liquid column of glass thermometers.

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

I. Date bottles of dehydrated microbiology media when received and opened. Do not use media beyond the manufacturer’s expiration date or within one (1) year from opening, whichever is sooner. Discard immediately if caked or otherwise deteriorated. Prepared, or prepackaged media are permitted.

J. Use plastic labware for microbiology that is clear and non-toxic.

K. 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 must be made according to specified analytical method requirements, but at least monthly, with a conductivity meter. All such quality checks must be recorded.

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

PARAMETER	LIMITS	FREQUENCY
resistivity	> 0.5 megohms/cm	monthly
Pb, Cd, Cr, Cu, Ni, Zn	< 0.05 mg/L per contaminant and < 0.1 mg/L total	annually
total chlorine residual	none detectable	monthly
Heterotrophic plate count	< 500/mL	monthly
bacteriological quality of reagent water.	ratio of growth rate: 0.8 to 3.0 (see Standard Methods, Section 9020B. This test is not required if laboratories use water that meets the criteria for Types I and II water as defined in Standard Methods Section 1080).	annually

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

N. Date all reagents and solutions when received and opened. Do not use materials beyond their expiration dates.

O. All laboratory prepared reagents and solutions must be labeled with preparation and expiration dates. No laboratory prepared materials shall be used beyond their expiration dates.

6.15 Safety & Security

A. The laboratory must establish and maintain adequate safety and security precautions.

B. Safety instructions must be present 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, but not limited to, the Occupational Safety and Health Administration standards for hazard communication, and occupational exposure to hazardous chemicals in laboratories.

C. Laboratory management and personnel must be given 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.

D. The laboratory must keep samples, standards, reagents, solvents, acids, chemicals, and data in restricted access areas.

E. The laboratory must supervise visitors, repairmen, and maintenance workers in restricted areas.

F. Implementation of the minimum security requirements stated in the rules and regulations related to the Medical Marijuana Program Administered by the Department of Business Regulation (230-RICR-80-5-1.4(G)(2) through (7)) shall be deemed by RIDOH to be substantially compliant with the security requirements of these Regulations.

6.16 Waste Disposal

A. Marijuana Waste and Destruction of Usable Medical Marijuana

1. Marijuana and marijuana product waste (including all liquid, chemical, hazardous, pesticide, manufacturing solvent and chemical waste containing any traces of marijuana) must be stored, secured, and managed in accordance with all applicable state, and local statutes, regulations, ordinances, or other legal requirements.

2. Prior to disposal, marijuana and marijuana product waste must be made unusable and any marijuana plant material made indistinguishable from other plant material. This may be accomplished by grinding and incorporating the marijuana plant waste with other non-consumable solid waste or other ground materials so the resulting mixture is at least fifty

percent non-marijuana waste by volume. Other methods to render marijuana waste unusable must be approved by DBR before implementing. Marijuana waste rendered unusable following an approved method may be delivered to a licensed solid waste disposal facility in Rhode Island for final disposition or disposed of in an alternative manner approved by DBR.

3. Destruction of marijuana and marijuana materials other than waste generated in the regular course of processing and/or manufacturing (such as destruction of whole plants, wet, or usable marijuana that are found to be more than statutory possession limits or destruction of a contaminated batch of medical marijuana product) must be in a manner acceptable to DBR, which may include consultation with law enforcement.

4. Destruction of marijuana and marijuana materials upon revocation or abandonment of the license must be specifically governed by DBR order or agreement and/or coordinated efforts with law enforcement.

B. The laboratory must manage medical waste per Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (250-RICR-140-15-1).

C. The laboratory must manage Hazardous Waste per the Department of Environmental Management "Rules and Regulations for Hazardous Waste Management".

D. Wastes, which are not classified as medical waste or hazardous waste or which are not otherwise regulated by law or rule, may be disposed in dumpsters or load packers provided the following precautions are maintained:

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. In addition, the pickup schedule must be maintained with more frequent pickups when required. The dumping site of waste materials must be in sanitary landfills approved by the Department of Environmental Management.

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. Also, the loading section must be construed and maintained to prevent rubbish from blowing away.

6.17 Sample Collection- General Requirements

A. Sample collection procedures must be applicable to any medical marijuana product that registered compassion centers or licensed cultivators may dispense, including, but not limited to, finished plant material; liquid concentrates, resins, edibles, waxes, creams, or other semi-solid or solid MIP products. The analytical laboratory sample collection must be conducted in a manner that provides representative samples so that laboratory testing of all medical marijuana products is accurate and product labelling requirements can be met. The analytical laboratory sample collector must document every sampling event and provide this documentation to the RIDOH upon request.

B. Analytical laboratories may be directed to perform emergency sampling and testing of medical marijuana products by the RIDOH or DBR. Additional costs must be charged to establishment where the medical marijuana was collected.

C. Marijuana cultivation and production facilities must provide floor plans to the analytical laboratory prior to sample collection that identifies the location and storage of all finished products in the production facility prior to distribution or dispensing.

D. Information that accompanies samples must be sufficiently detailed to permit identification and document chain of custody.

E. The analytical laboratory sample collector must collect representative samples of finished plant material products, liquid concentrates, and resins from each medical marijuana production batch for analysis. Each sample collected must be representative of the medical marijuana in its production batch.

F. Samples from each production batch must be collected in a ready-to-use condition, either for dispensing to patients, or for use as an intermediate or ingredient in making other products. Nothing in this paragraph should be interpreted to supersede any other provision or order requiring and/or authorizing testing at an earlier production stage. Samples of concentrates or oils must be collected following each production batch if they are to be sold, and before any further processing into MIPs.

G. After samples are collected, the establishment where the medical marijuana was collected must store the entire production batch in a quarantined, secure, cool, and dry location until analytical results are returned by the laboratory. The products must not be released for packaging or sale until the Medical Marijuana Tracking System provides notice of clearance to do so.

H. Sampling frequency is dictated by the production schedules, which may vary among registered compassion centers and licensed cultivators due to scale, product types dispensed, and patient demand. The registered compassion centers and licensed cultivators are responsible for implementing a production batch tracking approach that meets the requirements of these Regulations.

I. Analytical laboratory sample collectors must be able to determine that finished products they collect from compassion centers and licensed cultivators are representative of the production process and the finished product's tracking information matches its label.

J. The amount of sample to be collected for cannabinoid or contaminant testing may vary by analytical method and laboratory-specific procedures, therefore the licensed analytical laboratory will specify the minimum sample size required for evaluation. In all cases, the amount of sample collected by the laboratory must be large enough and sufficiently homogenized to provide a representative sample of the production batch but not in excess to raise issues with possible diversion or waste disposal.

K. The analytical laboratory must follow its approved sampling plan for collecting finished medical marijuana products. The sampling plan's procedures required for collecting samples of finished medical marijuana production batches must result in an accurate sample of the production batch. Production batches will vary in physical form (e.g., plant material, liquid extracts, concentrates and resins), density, and viscosity. Procedures for representative sampling of finished medical marijuana production batches must be based on those used for food products and herbal medicines in the manner described "General Guidelines on Sampling" CAC/GL50-2004 incorporated above at § 6.3(A) of this Part, and "Guidance on Obtaining Defensible Samples" incorporated at § 6.3(B) of this Part, and account for differences in the physical forms of the production batches as they relate to homogeneity and quantity.

6.18 Sample Collection Procedures

A. The analytical laboratory sample collector must create a new entry for each sampling event in a sample collection logbook or prepare sample collection forms for documentation of sample collection. Sample collection documentation must identify the sample collection date and start time, participating personnel, a general description of the product type and batch number sampled, a description of the sampling procedures used, and a record of batches that would potentially be impacted should analysis results indicate unacceptable contamination levels.

B. The analytical laboratory sample collector must identify or determine the tracking number of each finished production batch sampled and the number and amount of samples to be collected for each

C. The analytical laboratory sample collector must record the number of samples taken from each cultivation and/or production batch must be recorded in the sample collection logbook or forms.

D. The analytical laboratory sample collector must record the sample cultivation and production batch identifiers (ID) for each sample. The batch IDs will be included on sample labels. In addition to the batch ID, the analytical laboratory sample collector must create a unique sample ID for each sample. Sample identifiers must be unique for a given sample event. Record the batch and sample IDs in the sample collection logbook.

E. The analytical laboratory sample collector must prepare sample labels and affix them to sample containers immediately before sampling. The sample label must include the batch, sample identification, date / time of collection and by whom. The analytical laboratory sample collector's name, product type, collection method, and other details about the product, such as marijuana infused product type or production method must be recorded in documentation if not included on the sample label.

F. The analytical laboratory sample collector must wear disposable gloves, and not wear perfumes or creams to mitigate potential for contamination of samples.

G. Any tools that contact the samples must be made of stainless steel or other inert material to avoid potential contamination of the sample. Appropriate sample collection containers must be made of suitable materials.

H. The analytical laboratory sample collector must ensure that the sampling area is clean and decontaminated and lay out any tools and equipment needed.

I. The analytical laboratory sample collector must collect the samples from each cultivation or production batch one at a time following the approved sampling plan as described in §§ 6.11(D) and 6.17(K) of this Part.

J. The analytical laboratory sample collector must collect the sample using an appropriate tool. Do not touch the sample with your hands or allow the sample to touch anything that might cause cross contamination.

K. The analytical laboratory sample collector must record the time each sample was collected and record any difficulties, inconsistencies with the sampling plan, or other remarks (e.g., environmental conditions) that might be relevant to data analysis or quality assurance.

L. The analytical laboratory sample collector must clean any tools or equipment that come in contact with the finished plant material or other marijuana products before collecting the next sample to avoid cross contamination of samples.

M. The analytical laboratory sample collector must place all samples in clean, sealed sample collection containers that are large enough to hold the prescribed sample quantity with minimal headspace to preserve the chemical and biological composition. Sample containers must be firmly closed and appropriately labeled.

N. The analytical laboratory sample collector must maintain all samples on ice prior to and during transport to the analytical laboratory in a clean locked carrier.

O. The analytical laboratory sample collector must ensure that medical marijuana samples are secured and safe during transport. Transport vehicles must have a locked storage compartment within which the medical marijuana sample is secured. The sample collector must not stop for gasoline in-route between where the samples are collected and the analytical laboratory where the samples will be analyzed.

P. The analytical laboratory sample collectors must have their testing agent registration cards for the licensed cultivator/compassion center in their possession while collecting and transporting samples.

Q. The analytical laboratory sample collector must collect duplicate samples to provide verification of sampling and laboratory procedures. Specifically, a duplicate must be at least collected for 5 percent (1 per 20) of the samples collected for each medical marijuana product type. Duplicate samples are used to evaluate any variance in the sampling procedures. To ensure authenticity, QC samples must be taken on the same day, be derived from the same batch, and documented on the test results tracking sheet.

R. The analytical laboratory sample collector must complete the Chain-of-custody (COC) paperwork immediately prior to transporting the sample to the analytical laboratory. The sampler must record all sampling related information on the COC including:

1. date and time that each sample is collected;

2. identity of the sampler;

3. compassion center registration number or licensed cultivator license number, as applicable;

4. address and contact number of the marijuana production facility where sampling occurs;

5. identification of each sample collected;

6. identification of each product batch;

7. description of each sample collected;

8. location of each sampled finished product;

9. matrix of each sample collected;

10. approximate weight or quantity of each sample collected;

11. specific tests requested;

12. printed name and signature of production facility representative who relinquished the samples; and,

13. printed name and signature of the sample collector.

6.19 Sample Accessioning

A. Analytical laboratories receiving samples from the sample collector must complete the chain of custody forms (COC) to record accessioning and internal tracking of samples including the following information:

1. the laboratory internal tracking number or other identification;

2. printed name and signature of the person receiving the samples;

3. date and time of sample receipt;

4. condition of sample upon receipt;

5. type of tests requested;

6. the name, address, and license number of analytical laboratory to which sample(s) are forwarded for procedures not performed on the premises each of which must be numbered or otherwise appropriately identified;

7. sample tracking through each stage of storage, analysis, and disposal;

8. date laboratory tests are performed;

9. the analytical laboratory test results;

10. date of reporting; and,

11. sample test reports.

B. The records of samples must contain the completed chain of custody forms (COCs) and original completed sample collection forms.

6.20 Sample Preparation

A. Analytical laboratories must have a designated area of the facility dedicated to preparing medical marijuana product samples for analysis. Sample preparation areas must be equipped with the supplies and equipment to properly handle samples during preparation including:

1. disposable gloves;

2. decontaminated tool(s) such as disposable pipettes and plastic or stainless steel spatulas, knives, and sampling spears;

3. decontaminated stainless steel bowls and implements to homogenize the product by stirring, chopping, or grinding;

4. clean, decontaminated surfaces for sample processing;

5. decontaminated sample containers appropriate for the analyses required;

6. container labels and pens with indelible ink; and,

7. supplies to thoroughly clean, decontaminate, and dry sample preparation equipment between samples.

B. Follow these steps to prepare each sample type:

1. Wear disposable gloves to avoid contaminating samples. Do not wear creams or perfumes.

2. Ensure that the sample preparation area is clean and decontaminated and lay out any tools and equipment needed.

3. Place the sample 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.

4. Prepare the sample for analysis using an appropriate decontaminated tool. Do not touch the sample with your bare hands or allow the sample to touch anything that might cause cross contamination.

5. Clean any tools or equipment that come in contact with the finished plant material or other marijuana products before preparing the next sample.

6. Place all samples in clean, air tight sample containers that are large enough to hold the prescribed sample quantity with minimal headspace. Close and label sample containers.

7. Preserve the chemical and biological composition of the samples, by refrigerating samples at < 6 º C.

8. Ensure samples of finished medical marijuana plant and edible products are homogenous with respect to distribution of cannabinoids or contaminants.

9. Thoroughly stir or mix before quantitatively measuring a portion for analysis. Grind and thoroughly mix solid and semi-solid products. Use a grinding device that minimizes loss (e.g., leaching of resins) and, thoroughly clean the grinding device after each use.

10. For finished medical marijuana products that are distributed in a ground form, quarter the product batch sample. Quartering involves heaping the ground product, dividing the heap into four equal quarters, and selecting samples from two 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. Do not melt resin and other solids 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.

12. Homogenize laboratory samples of edibles prior to testing such that the sample is representative of the finished product batch. Mix or quarter homogenized samples in a manner like the procedure described in § 6.20(B)(10) of this Part. If individually packaged edibles are sampled from a production batch, combine multiple packaged products and prepare such that the distribution of cannabinoids or contaminants is representative of the production batch.

13. When subsamples are required, composite (combine) subsamples, if possible, and mix to obtain a quantity sufficient for evaluation. The quantity sufficient for evaluation may vary by analytical method and laboratory-specific procedures, therefore the analytical laboratory must define the minimum sample quantity required for evaluation.

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 analytical laboratory as samples for analysis. In some cases, the analytical laboratory may combine extracts or digestates prepared from the solid subsamples and analyze the volumetrically combined extract / digestate as a composite.

6.21 Sample Analysis

A. General Requirements

1. All medical marijuana product samples described in these regulations must be analyzed by analytical laboratories licensed by the RIDOH.

2. Use only chemical standards manufactured by a provider acceptable to the Director to prepare calibration and quality control standards. Analytical laboratories must maintain standard preparation records and the certificates of analysis for all chemical standards, reference materials and reagents for at least five years.

3. Licensed analytical laboratories must demonstrate the ability to perform the quantitative analytical methods approved by RIDOH, and to provide defensible documentation and quality assurance.

B. Approved Methods

1. Methods approved by RIDOH for the analysis of cannabinoids and contaminants in medical marijuana products are listed in Table 1. Equivalent test procedures may be followed if the laboratory has demonstrated the analysis is an acceptable alternative to normally used reference methods to the satisfaction of RIDOH.

2. Table 1: List of Approved Methods for the Analysis of Cannabinoids and Contaminants.

Analytical Component (where applicable, notes are listed in parenthesis, and described below in § 6.21(B)(3) of	Methodology (where applicable, notes are listed in parenthesis and described below in § 6.21(B)(3) of this Part)		Agency or Organization (see Definitions § 6.4 of this Part) Procedures (listed in parenthesis and described below in § 6.21(B)(3) of this Part)				
		FDA	AOAC	AHP	USP	USDA	WHO

this Part)							
Cannabinoids							
Δ9-THC, THCa, CBD, CBDa (a)	LC-DAD (b)			(b)			
	LC – MS, LC-MS/MS (b)			(b)			
	GC/ FID (b)			(b)			
Metals							
Arsenic--Total mg/L	Digestion followed by ICP/MS (c)	(f)	(g), (h)		(j)		
Cadmium--Total mg/L	Digestion followed by ICP/MS (c)	(f)	(g), (h)		(j)		
	Digestion followed by Flame AA (c)		(i)				
	Digestion followed by Graphite Furnace (c)	(d)	(i)				
Lead--Total, mg/L	Digestion followed by ICP/MS (c)	(f)	(g), (h)		(j)		
	Digestion followed by Flame AA (c)		(i)				
	Digestion followed by Graphite Furnace (c)	(d)	(i)				
Mercury--Total, mg/L	Digestion followed by ICP/MS (c)	(f)	(g), (h)		(j)		

	Cold Vapor AA (c)	(e)					
Pesticides and Plant Growth Regulators							
Pesticides and Plant Growth Regulators - mg/L	QuEChERS, GC-MS, GC-MS/MS	(k)	(l), (m)			(o)	
	QuEChERS,LC-MS, LC-MS/MS	(k)	(l), (m)			(o)	
	QuEChERS GC-ECD, GC-NPD, LC-FLD	(k)	(n)				(p)
Water Activity							
Water Activity	Humidity Meter, Hygrodynamic Hygrometer		(q)				
Microbiological							
Total Viable Aerobic Bacteria	Culture and enumeration	(r)			(w), (x), (y)		(z)
Total Yeast and Mold	Culture and enumeration	(s)			(w), (x), (y)		(z)
Total Coliforms	Culture and enumeration	(t)					
Bile-tolerant Gram-negative Bacteria	Culture and enumeration				(w), (x)		(z)

E. coli (pathogenic)	Culture	(u)					(z)
Salmonella	Culture	(v)					(z)
Residual Solvents							
Residual Solvents	Headspace GC/FID				(aa)		

a. Table 1 Key:

(1) ECD = Electron capture detector

(2) FLD = Fluorescence detector

(3) GC = Gas chromatography

(4) MS = Mass spectrometry

(5) NPD = Nitrogen phosphorous detector

(6) LC = Liquid chromatography.

3. Procedures and Notes for Table 1:

a. Quantitative analysis including the percentage of Δ9-tetrahydrocannnabinol (Δ9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa) of the total amount of THC.

b. 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.

c. 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).

d. 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."

e. 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."

f. 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".

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

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

i. 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).

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

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

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

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

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

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

p. EPA Index of Residue Analytical Methods (RAM)

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

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

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

t. FDA. 2013. Biological Analytical Manual, Chapter 4 Enumeration of E. coli and Coliform.

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

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

w. USP. 2008. “Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.” USP 31, Chapter 61.

x. USP. 2008. “Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms.” USP 31, Chapter 62.

y. USP. Undated-b. “Articles of Botanical Origin.” USP 36, chapter 561.

z. WHO 2007 guidelines for assessing quality of herbal medicines regarding contaminants and residues. Annex 5

aa. USP. Chemical Tests. Chapter 467 Residual Solvents

C. Cannabinoid Profile Analysis- Additional Information/Requirements

1. All finished medical marijuana plant components, extracts and concentrates must be quantitatively analyzed following methods described in § 6.21(B) of this Part, to determine the total THC and its cannabinoid profile in the product. Although many cannabinoids and related compounds are present in the cannabis plant, characterization of the cannabinoid profile of the total THC in the medical marijuana product must include, at a minimum, the percentage of Δ9-tetrahydrocannnabinol (Δ9-THC), cannabidiol (CBD), tetrahydrocannabinolic acid (THCa) and cannabidiolic acid (CBDa). Percentage amounts of other cannabinoids may be reported, but are not required.

D. Metals Analysis- Additional Information/Requirements

1. Finished medical marijuana plant products must be tested for metals including arsenic, cadmium, lead, and mercury following methods described in § 6.21(B) of this Part. 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.

2. The analytical limit for finished medical marijuana products including finished plant materials, resins, and concentrates is specified in § 6.21(D)(2)(a) of this Part (Table 2).

    a. Table 2: Analysis Requirements for Metals in Finished Medical Marijuana Products for All Uses. Analytical results which exceed these upper limits must be reported with a qualifier indicating the contaminant measured in the medical marijuana product is above the concentration allowable for the intended use.

Metal	All uses * Upper Limit (µg/kg)	Marijuana-Infused Products Only ** Upper Limit (µg/kg)
Arsenic (inorganic)	200	1500
Cadmium	200	500
Lead	500	1000
Mercury	100	1500
* These limits apply to finished plant material, cannabis resin, cannabis concentrates intended for ingestion, inhalation or dermal application. These limits are based on inhalation limits described in USP<232> Elemental Impurities—Limits.		
** These limits apply to Marijuana-Infused Products only. These limits are based on limits specified in USP<2232> Elemental Contaminants in Dietary Supplements.		

E. Pesticides Residues Analysis- Additional Information/Requirements

1. Analytical laboratories must quantitatively analyze production batches of finished plant material and extracts, resins, and concentrates for residues of prohibited pesticides following methods described in § 6.21(B) of this Part. At a minimum, samples of finished plant material must be tested for the pesticides, including plant growth regulators listed in § 6.21(E)(1)(a) of this Part (Table 3), which includes the appropriate analytical methods for each of the listed pesticides. These pesticides were identified by AHP (2014) as commonly used in cannabis cultivation.

    a. Table 3: 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	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	283594-90-1	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

b. Table 3 Key:

(1) ECD = Electron capture detector

(2) FLD = Fluorescence detector

(3) GC = Gas chromatography

(4) MS = Mass spectrometry

(5) NPD = Nitrogen phosphorous detector

(6) LC = Liquid chromatography

2. Analytical laboratories must analyze pesticides in addition to those in Table 3 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, analytical laboratories conducting medical marijuana testing in Rhode Island must analyze as many compounds on the USDA target analyte list for organic food as possible. Analytical laboratories must follow procedures listed in § 6.21(B)(3) of this Part or their equivalent.

3. The upper limit for pesticides and plant growth regulators is less than or equal to 10 parts per billion (ppb).

4. A laboratory 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 percent 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 such circumstances, RIDOH must be notified regarding the specific pesticides to which this method is being applied.

F. Water Activity Analysis- Additional Information/Requirements

1. Finished medical marijuana plant material must be tested for water activity following methods described in § 6.21(B) of this Part. See the definition of water activity in § 6.4 of this Part. The water activity upper limit for unbound water is equal to or less than 0.6aW.

G. Microbiological Contaminants Analysis- Additional Information/Requirements

1. Finished medical marijuana plant products must be tested for microbiological contaminants following methods described in § 6.21(B) of this Part. Methods used must be consistent with the following United States Pharmacopeia (USP) chapters:

   a. USP Chapter <61>: Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. USP 36, Chapter 6, and

   b. USP Chapter <62>: Microbiological Examination of Nonsterile Products: Tests for specified Microorganisms. USP 36, Chapter 62

2. Limits for microbiological contaminants are listed in § 6.21(G)(2)(a) of this Part (Table 4).

   a. Table 4: Upper Limits for Microbiological Contaminants.

Cannabis Material	Total Viable Aerobic Bacteria (CFU)/g)	Total Yeast and Mold (CFU/g)	Total Coliforms (CFU/g)	Bile-tolerant Gram Negative Bacteria (CFU/g)	E. Coli (pathogenic strains) and Salmonella spp.
Finished Plant Material	100,000	10,000	1,000	1,000	Not detected in 1 g of sample

3. Notes for Table 4:

a. Analytical limits are based on American Herbal Pharmacopoeia (AHP) (2014).

b. CFU means colony forming unit.

H. Residual Solvents Analysis- Additional Information/Requirements

1. Finished medical marijuana extracts, resins and concentrates must be tested for residual solvents when solvent have been used in the production process following methods described in § 6.21(B) of this Part.

2. Analytical laboratories are required to test for the residual solvents listed in § 6.21(H)(3) of this Part (Table 5) unless it can document that no solvents were used in the cannabis oil production process.

3. Table 5: 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 tetrachloride **	56-23-5	4	Methylethylketone	78-93-3	5000

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 § 6.21(H)(4) of this Part for further information.					
** Class 1 solvents provided by USP Chapter <467> may not be used in the production of any medical marijuana product.					

4. The upper limits for residual solvents in Table 5 are given as milligrams of residual solvent per kilogram of cannabis oil. The upper limits in Table 5 are based on residual solvent standards provided by the USP Chapter <467>, the International Conference on Harmonization (ICH, 2011), and AHP (2014).

a. Class 1 solvents may not be used in the production of any medical marijuana product.

5. Analyses to determine residual solvent concentrations in medical marijuana products must be performed in accordance with the methods identified in USP Chapter <467>.

6.22 Quality Control

A. 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.

B. Initial Calibration

1. 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 analytical laboratories must at a minimum perform a three-point initial calibration spanning a concentration range from below to above the maximum allowable contaminant concentration. Analytical laboratories 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.

C. Continuing Calibration

1. 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 ten 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. Analytical laboratories must document the calibration performance and quality control results for all analyses.

6.23 Test Reporting

A. Analytical laboratories must report all testing results including all information necessary to determine product compliance to the Department of Business Regulation Medical Marijuana Program Tracking System and the medical marijuana producer including registered compassion centers and licensed cultivators.

B. Include the following in the laboratory data package: case narrative, chains-of-custody, and summary of analytical results.

1. A case narrative written on laboratory letterhead, must describe any sample receipt, preparation, or analytical issues encountered as well as any method non-conformances or exceedance of QA/QC criteria used by the laboratory. The narrative must identify the preparation and analytical methods utilized by the laboratory. The narrative must include a signed statement by an authorized laboratory representative as to the accuracy, completeness, and compliance with the methods of the results presented.

2. Chains-of-custody (COC) information or other paperwork indicating requested analyses and documentation of sample collection and receipt must be reported with the laboratory's results.

3. Laboratory reports must clearly identify the name, address, and license number of the laboratory (which may be a subcontracted laboratory) that performed the test(s), and must include the results and the date of the reporting.

4. Multipage reports must be paginated.

5. 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 date(s), where applicable, and analysis date(s).

6. Analytical results, which exceed the upper limit described in §§ 6.21(D)(2), 6.21(E)(3), 6.21(F)(1), 6.21(G)(2), and 6.21(H)(4) of this Part must be reported with a qualifier indicating the contaminant measured in the medical marijuana product is above the allowable concentration.

7. The laboratory data package must include sufficient data to evaluate the laboratory results, including a summary of laboratory QA/QC results.

8. Medical marijuana products, which is determined to be out of compliance may be resampled for follow-up testing. A production batch may be retested once and records of the original analysis must be retained.

6.24 Variance Procedure

A. The RIDOH may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in specific instances where it is found that literal enforcement of such provisions will result in unnecessary hardship to the applicant and such variance will not be contrary to

state regulations, the public interest, public health, or health and safety of individuals.

B. A request for variance must be made in writing, setting forth in detail the basis of the request.

C. RIDOH shall act within ninety (90) days of receipt of the completed request for variance. RIDOH must notify the applicant by certified mail of its approval, or in case of a denial, a hearing date, time, and place may be scheduled if the applicant appeals the decision.

6.25 Violations

In addition to revocation or suspension of certificates granted under these Regulations, any person who violates the statutory or regulatory provisions herein will be subject to the sanctions of R.I. Gen. Laws § 23-16.2-13.

6.26 Rules Governing Practices & Procedures

A. All hearings and reviews required under the provision of these Regulations shall be held in accordance with the rules and regulations for Practices and Procedures Before the Rhode Island Department of Health (Part 10-05-4 of this Title).

B. Enforcement hearings shall be handled in accordance with R.I. Gen Laws § 23-1-22.

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TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER XXX - OLD REGULATIONS WHICH WERE NOT ASSIGNED CHAPTER-SUBCHAP-PART

SUBCHAPTER XX - OLD REGULATIONS WHICH WERE NOT ASSIGNED CHAPTER-SUBCHAP-PART

PART 9134 - Licensing Analytical Laboratories for Sampling and Testing Medical Marijuana (216-RICR-60-05-6)

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