



DEPARTMENT OF HEALTH OFFICE OF MEDICAL MARIJUANA USE



Application for Marijuana Testing Laboratory Certification

The certification or renewal of a marijuana testing laboratory by the department shall mean:

A marijuana testing laboratory or an applicant for certification who has received written notification from the department that its application for certification or application for renewal as a marijuana testing laboratory has been found to be in compliance with the provisions of sections 381.986 and 381.988, F.S., and department rules. Notification may only be provided by the department after the following requirements have been met:

- (1) A marijuana testing laboratory submitted a completed application accompanied by an application fee;
- (2) A marijuana testing laboratory is not owned or controlled by a medical marijuana treatment center;
- (3) A marijuana testing laboratory submitted proof of an accreditation or a certification;
- (4) All owners and managers of a marijuana testing laboratory have submitted and passed a level 2 background screening pursuant to section 381.988(1)(d), Florida Statutes; and
- (5) A marijuana testing laboratory demonstrated to the department the capability of meeting the standards for certification.

A marijuana testing laboratory must adhere to the requirements of sections 381.986(8)(d), 381.986(8)(e)10. d., 381.986(8)(g), and 381.988, F.S., this rule, and representations made within its initial application. A certified marijuana testing laboratory may request a variance or waiver from the representations made in its application pursuant to section 120.542, F.S.

- (1) Marijuana testing laboratories may request a variance from its initial application by submitting to the department a modified version of its approved application for marijuana testing laboratory certification, with the all modifications clearly labeled. Consideration of such a request shall be based upon the individual facts and circumstances surrounding the request. A variance may not be granted unless the requesting marijuana testing laboratory can demonstrate to the department that it has a proposed alternative to the specific representation made in its application which fulfills the same or a similar purpose as the specific representation in a way that the department can reasonably determine will not be a lower standard than the specific representation in the application.

Public Records

MTL applications submitted to the department are public records. Any exemption to public records law must be identified at the time the application is submitted. To claim any public records exemption, the applicant must provide a redacted copy of the application and all attachments with a clearly identified statutory basis for each exemption sought.

Unless information falls under another public records exemption, failure to specify and identify information as trade secret or confidential business information, or failure to provide a redacted copy of this MTL application, including all attachments, at the time of submission will result in the release in response to public records requests.



DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE



Persons or entities applying for certification as a marijuana testing laboratory must:

- (1) Complete and submit this form, Form DH####-OMMU-###/####, "Application for Marijuana Testing Laboratory Certification." Incomplete applications for certification will be denied.
(2) Submit a non-refundable, non-prorated application fee of \$####. The non-refundable, non-prorated renewal fee of \$####; must be submitted to the department on the same business day as the entity's submission of Form DH####-OMMU-###/####. Failure to submit a non-refundable, non-prorated application fee of \$#### timely is ground for denial of the associated application for certification.
(3) Request, and undergo an inspection of its testing facility by the department pursuant to subsection (8) to determine that it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations made in its application for certification.
(4) Deliver applications, fees, exhibits, and supporting documents together to the Department of Health, ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida.

Marijuana testing laboratories applying for biennial renewal must:

- (1) Submit documentation evidencing that it was previously certified as a marijuana testing laboratory that meets the requirements of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., and department rules;
(2) Complete and submit this form, Form DH####-OMMU-###/####, "Application for Marijuana Testing Laboratory Certification." Incomplete applications for certification will be denied.
(3) Submit a non-refundable, non-prorated non-refundable, non-prorated renewal fee of \$####. The non-refundable, non-prorated renewal fee of \$####; must be submitted to the department on the same business day as the entity's submission of Form DH####-OMMU-###/####. Failure to submit timely may result in suspension or revocation of certification.
(4) Request, and undergo an inspection of its testing facility by the department pursuant to subsection (8) to determine that it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations made in its application for certification.
(5) Deliver applications, fees, exhibits, and supporting documents together to the Department of Health, ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida.

Instructions

This form is divided into two sections.

Section 1 - Applicant General Information

Section 2 - MTL Requirements & Supporting Documentation

- Complete each section of the form and attach all required documentation in order, based on each section's requirements.
Label any attachments using the names of each applicable section.
An application must be submitted in portable document format ("PDF").
If mailed to the department at the address listed below, a copy of the MTL application in PDF format must be included on a USB Flash Drive.
A MTL application must be submitted either electronically to: OMMULicenseOperation@flhealth.gov Or mailed to The Office of Medical Marijuana Use at: 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida 3239

Application fee

- Provide a non-refundable \$##### application fee in the form of a money order or cashier's check made payable to the Florida Department of Health;



DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE



Section 1 – Applicant General Information

REGISTERED BUSINESS NAME			
DOING BUSINESS AS			
STREET ADDRESS OF PROPOSED TESTING FACILITY			
CITY	COUNTY	STATE	ZIP

NAME OF INDIVIDUAL COMPLETING THIS Application			
BUSINESS NAME			
STREET ADDRESS			
CITY	COUNTY	STATE	ZIP
EMAIL	PHONE NUMBER AND EXTENSION		
DATE			



**DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE**



Section 2 – MTL Requirements & Supporting Documentation

Instructions

To identify your selection and confirm all documentation has been supplied, clearly mark in the box left of the variance subject.

Example:

1. Accreditations and Certifications

Definitions:

Testing facility – The location of a real property or any area within a real property to be utilized by a certified marijuana testing laboratory for any function related to the preparation, analysis, storage, and waste management of useable whole flower marijuana, derivative product, or edibles.

Testing Field - The suite of analytes tested within a particular matrix category. For the purposes of this rule, the testing categories are microbiology, mycotoxins, residual solvents, heavy metals, agricultural agents, moisture and water activity, and cannabinoid profile.

Each marijuana testing laboratory may operate only one testing facility. A testing facility must be ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accredited. Accreditation must demonstrate that the applicant is qualified to analyze one or more of the following testing fields:

1. microbiology;
2. mycotoxins;
3. residual solvents;
4. metals;
5. pesticides;
6. water activity;
7. moisture;
8. filth and foreign material; and
9. cannabinoid potency.

Select the ISO/IEC accreditation attained by applicant:

	Current and valid ISO/IEC 17025:2017, accreditation; or
	Current and valid ISO/IEC 17025:2005, accreditation.

Provide the following documentation associated with the applicant’s ISO/IEC accreditation:

	All material submitted for the most recent ISO/IEC 17025:2017 or ISO/IEC 17025:2005 audit;
	Documentation identifying the entity or person that awarded the ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accreditation, to include recognition by the International Laboratory Accreditation Cooperation (ILAC);
	Initial certification report or the most recent audit report from an ILAC accredited auditing body.



DEPARTMENT OF HEALTH OFFICE OF MEDICAL MARIJUANA USE



2. Proficiency Testing

Definitions:

Matrix group - The components of a testing sample other than the analytes of interest. For the purposes of this rule, the matrix groups are usable whole flower marijuana, derivative products, and edibles.

Proficiency testing - Testing of unknown samples by an applicant or marijuana testing laboratory, to determine the accuracy of the analysis for specific analytes and matrices. Unknown samples used for proficiency testing must be provided by an ISO/IEC 17043 accredited body.

Testing facility - The location of a real property or any area within a real property to be utilized by a certified marijuana testing laboratory for any function related to the preparation, analysis, storage, and waste management of useable whole flower marijuana, derivative product, or edibles.

Testing field - The suite of analytes tested within a particular matrix category. For the purposes of this rule, the testing categories are microbiology, mycotoxins, residual solvents, heavy metals, agricultural agents, moisture and water activity, and cannabinoid profile.

Each marijuana testing laboratory may operate only one testing facility. A testing facility must be ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accredited. A marijuana testing laboratory may only conduct tests and perform analyses of testing fields within matrix groups at approved testing facilities. Tests and analyses of testing fields within matrix groups must be supported by documentation of two satisfactory analyses of the three most recent proficiency testing administered by an ISO/IEC 17043:2010 accredited body.

1. Proficiency test sample results that are within the acceptance limits established by the contracted ISO/IEC 17043 accredited body are satisfactory.
2. A certified marijuana testing laboratory must participate in at least two proficiency testing rounds from an ISO/IEC 17043 accredited body per calendar year beginning on the date of issuance or renewal of the certification. Consecutive rounds of proficiency testing may not occur at less than seven-month intervals, as determined by the closing dates of each proficiency testing attempt.
3. If a marijuana testing laboratory reports more than one result for a field of proficiency testing on a proficiency testing round, any unsatisfactory result constitutes a failed testing attempt for the corresponding certified or pending field of accreditation.
4. A marijuana testing laboratory that unsatisfactorily completes proficiency testing shall not, for 30 days ("probationary period"), test or provide results for any analyte, matrix, or other measurement for which its analysis was unsatisfactory. During the probationary period, the laboratory must undertake an internal investigation to determine the reason for the unsatisfactory test result and may complete additional proficiency testing including any analyte or matrix that failed. Findings of the internal investigation must be provided to the department.
5. If a laboratory that completes proficiency testing during the probationary period receives unsatisfactory results for the analyte or specific matrix, the laboratory shall not test or provide results for that analyte or matrix for 180 days from the date of the notice failure. During the 180 days, the laboratory may cure any deficiencies and complete proficiency testing for any failed analyte, matrix, or other measurement.
6. The failure to complete proficiency testing and report to the department satisfactory results for failed analytes, matrices, or other measurements within 180 days of the notice of failure is revocation of the marijuana testing laboratory's certification.



**DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE**



2. Proficiency Testing (continued)	
For each of the following fields within each matrix category, provide documentation evidencing satisfactory results for the two most recent proficiency tests administered by an ISO/IEC 17043:2010 accredited body:	
Useable whole flower marijuana	
<u>Microbiology</u>	<u>Mycotoxins</u>
<u>Pesticides</u>	<u>Metals</u>
<u>Moisture</u>	<u>Water activity</u>
<u>Cannabinoid potency</u>	<u>Filth and foreign material</u>
Derivative products	
<u>Microbiology</u>	<u>Mycotoxins</u>
<u>Residual solvents</u>	<u>Metals</u>
<u>Pesticides</u>	<u>Water activity</u>
<u>Moisture</u>	<u>Filth and foreign material</u>
<u>Cannabinoid potency</u>	
Edibles	
<u>Microbiology</u>	<u>Mycotoxins</u>
<u>Residual solvents</u>	<u>Metals</u>
<u>Pesticides</u>	<u>Water activity</u>
<u>Moisture</u>	<u>Filth and foreign material</u>
<u>Cannabinoid potency</u>	



DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE



3. Personnel

Definitions:

Laboratory Director - An individual that oversees all analysts, employees, and functions of testing low-THC cannabis, medical marijuana, derivative product, and edibles, and is compensated for the performance of such duties.

Analyst - An employee of a marijuana testing laboratory whose duties include conducting analyses, analyzing and recording results, maintaining testing-related workspaces and equipment, and maintaining marijuana samples in accordance with the requirements of this rule.

Sampler - A marijuana testing laboratory employee who collects samples of marijuana from a medical marijuana treatment center for testing and has undergone specific training to fulfill this function.

Employee - Any person whose duties involve activities or responsibilities that support the function of testing low-THC cannabis, medical marijuana, derivative product, or edibles and is compensated for the performance of such duties.

Provide an organizational chart illustrating the supervisory structure of each physically independent testing facility operated by the applicant, to include the identities of all laboratory directors, analysts, samplers, and employees. Provide sufficient information to clearly describe the duties and responsibilities of each position listed.

Provide documentation evidencing that each laboratory director meets the following requirements:

Only oversees one of the applicants physically independent testing facility;

Is 21 years of age or older;

Has passed level 2 background screening pursuant to section 435.04, F.S., and has not been found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of another jurisdiction;

Holds a bachelor's degree in a natural science, to include, but not be limited to, biology, chemistry, physics, engineering, or environmental sciences, or holds a current certification as Florida Board of Clinical Laboratory Personnel;

A minimum of five (5) years of experience in a regulated laboratory environment sufficient for any accreditation required by this rule.

Provide documentation evidencing that each analyst meets the following requirements:

Is 21 years of age or older;

Has passed level 2 background screening pursuant to section 435.04, F.S., and has not been found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of another jurisdiction;

Holds a bachelor's degree in a natural science, to include, but not be limited to, biology, chemistry, physics, engineering, or environmental sciences, or holds a current certification as Florida Board of Clinical Laboratory Personnel;

Has been provided specific training on the applicant's standard operating procedures for sampling and security.



DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE



3. Personnel (continued)	
Provide documentation evidencing that each sampler meets the following requirements:	
<input type="checkbox"/>	Is 21 years of age or older;
<input type="checkbox"/>	Has passed level 2 background screening pursuant to section 435.04, F.S., and has not been found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of another jurisdiction;
<input type="checkbox"/>	Holds a high school diploma from a state-approved and accredited public or private school, or an associate degree from an institution accredited by a federally- or nationally-recognized accrediting or state agency, or holds a current certification as a Florida Board of Clinical Laboratory Personnel.
<input type="checkbox"/>	Has been provided specific training on the minimum requirements for sampling, incorporated in the Sampler Manual, and the applicant's standard operating procedures for sampling and security.
Provide documentation evidencing that each employee meets the following requirements:	
<input type="checkbox"/>	Is 21 years of age or older;
<input type="checkbox"/>	Has passed level 2 background screening pursuant to section 435.04, F.S., and has not been found guilty of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of another jurisdiction;
<input type="checkbox"/>	Holds a high school diploma from a state-approved and accredited public or private school, or an associate degree from an institution accredited by a federally- or nationally-recognized accrediting or state agency, or holds a current certification as a Florida Board of Clinical Laboratory Personnel.



**DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE**



4. Infrastructure and Security

Definitions:

Secure storage - The segregation of useable whole flower marijuana, derivative product, or edibles in a manner that prevents access from unauthorized persons, compromise of the product's integrity, or premature spoilage.
Testing facility – The location of a real property or any area within a real property to be utilized by a certified marijuana testing laboratory for any function related to the preparation, analysis, storage, and waste management of useable whole flower marijuana, derivative product, or edibles.

Each marijuana testing laboratory may operate only one testing facility. A testing facility must be ISO/IEC 17025:2017 or ISO/IEC 17025:2005 accredited. A marijuana testing laboratory may only conduct tests and perform analyses of testing fields within matrix groups at approved testing facilities. Tests and analyses of testing fields within matrix groups must be supported by documentation of two satisfactory analyses of the three most recent proficiency testing administered by an ISO/IEC 17043:2010 accredited body. A testing facility must undergo an inspection by the department pursuant to subsection (8) to determine that it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations made in its application for certification.

Provide a list including all of the applicants proposed testing facilities. For each testing facility listed include the address, city, county, zip code, and the identity of the laboratory director.

For each proposed testing facility, provide a floor plan, to include the location of all secure storage areas and all security measures. Security measures must demonstrate the applicant's ability to maintain adequate controls against diversion, theft, or other loss of marijuana, the tampering or compromise of samples, and the tampering or compromise of testing equipment and materials, and must demonstrate compliance with the following security requirements to ensure the safety and security of all proposed testing facilities and secure storage areas:

A fully operational security alarm system that secures all entry points and perimeter windows and is equipped with motion detector and duress, panic, and hold-up alarms.

A fully operational video surveillance system that records continuously 24 hours a day, and meets the following criteria:

Cameras are fixed in a place that allows for the clear identification of persons and activities in controlled areas of any testing facility and secure storage area;

Cameras are fixed at entrances and exits to the premises, record from both indoor and outdoor, or ingress and egress, vantage points;

Recorded images legibly and accurately display the time and date; and

Retain video surveillance recordings for at least 45 days or longer.



**DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE**



4. Infrastructure and Security (continued)

<input type="checkbox"/>	Fully operational dusk-to-dawn safety lighting on the exterior of the facility that provides reasonable illumination to the areas directly around the premises, including all points of ingress and egress.
<input type="checkbox"/>	All marijuana and marijuana samples are stored in a secured, locked room or a vault in a manner that does not accelerate spoilage or promote other degradation.
<input type="checkbox"/>	Make available at least two laboratory employees accept useable whole flower marijuana, derivative product, and edibles for testing at the testing facility.
<input type="checkbox"/>	At least two employees, or two employees of a contracted security agency, are on the testing facility premises when marijuana is received, when marijuana is tested, and during all normal business hours.
<input type="checkbox"/>	Each employee wears a legible photo identification badge at all times while on the premises.
<input type="checkbox"/>	Any non-employee natural persons with access to the premises of the marijuana testing laboratory must brandish an identification badge clearly indicating their status as a visitor, and be accompanied by an employee at all times;
<input type="checkbox"/>	Each employee has training in and access to the applicant's alcohol and drug-free workplace policy.
<input type="checkbox"/>	Each employee has training in and access to the applicant's theft and diversion policies and procedures, and have been made aware of the requirement to report to local law enforcement within 24 hours notification or knowledge of the apparent theft, diversion, or loss of marijuana.



**DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE**



5. Operations and Accountability

Quality assurance - A system developed either by the applicant or marijuana testing laboratory to ensure that products and services delivered are as accurate and precise as possible.
Quality control – A system developed in accordance with ISO 17025 standards, to verify that the required level of quality in analyses are met and maintained. Such verification shall include determining that appropriate equipment and instruments are used, continued inspection and overview of all facets of the testing process, and undertaking corrective action as necessary. Quality control samples should contain, where applicable, method blank, duplicate lab fortified blank, duplicate matrix spikes, and duplicate testing samples.

Documentation of implemented quality assurance and quality controls. Quality assurance and quality controls must be contained within written standard operating procedures and be in accordance with any accreditation required by this rule.

Each marijuana testing laboratory shall develop and maintain a written quality-assurance program manual which addresses every aspect of its quality assurance program, to include, but not limited to:

- Quality control procedures;
- Laboratory organization;
- Laboratory employee training;
- Laboratory employee responsibilities;
- Objectives for measurement data;
- Data and result traceability;
- Preventative maintenance of equipment;
- Performance audits, to include internal and external laboratory auditing;
- Corrective action;
- Retention and maintenance of quality assurance records; and
- Secure marijuana storage.

Documentation evidencing that the applicant has policies and procedures in place to ensure that once a year or whenever a change of method, equipment, or laboratory director occurs, the laboratory director or authorized employee shall review, amend as necessary, and approve of the marijuana testing facility's laboratory quality assurance program.

Documentation evidencing that the applicant performs internal quality assurance and quality control audits at least once every year. Internal audit results shall be provided to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov within five (5) business days of the completion of the audit.



DEPARTMENT OF HEALTH OFFICE OF MEDICAL MARIJUANA USE



5. Operations and Accountability (continued)

Documentation evidencing that the applicant has policies and procedures in place to ensure that testing equipment shall be used and maintained according to the manufacturer's instructions and shall be calibrated pursuant to the requirements of any accreditation under which it is operated. Marijuana testing laboratories shall retain records of all equipment repairs, maintenance, and calibrations.

Documentation evidencing that the applicant performs internal audits of all laboratory equipment, facilities, personnel, and security occur at least once every year. Audit results shall be provided to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov, by the internal auditor that conducted the audit within five (5) business days of the completion of the audit.

Documentation of the establishment of a tracking system to document the complete chain of custody of marijuana samples from receipt through disposal. The applicant's tracking system must be capable of integration with the department's seed-to-sale tracking system, once implemented. Chain-of-custody entries must show the date, time, name of employee or employees handling the sample, the condition of the sample, the condition of any container or packaging the sample was transported or stored in, the location of the sample, the sample's unique identifier, and the seed-to-sale information from the medical marijuana treatment center.

Documentation of a procedure to dispose of laboratory waste. Any marijuana in possession by a marijuana testing laboratory but undergoing no preparatory or analytical procedures ("non-laboratory marijuana waste") must be disposed of in accordance with department rule. Dry flower non-laboratory marijuana waste must be ground and mixed with general waste to a 50:50 ratio. Liquid non-laboratory marijuana waste may be mixed with methylene chloride to a 50:50 ratio and disposed of as hazardous waste.



DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA USE



5. Ownership	
Applicants must provide sufficient documentation to the department to provide reasonable assurance that any person or entity seeking certification as a marijuana testing laboratory is not owned and/or controlled by a medical marijuana treatment center.	
<input type="checkbox"/>	Provide a fully diluted capitalization table. Fully diluted capitalization table shall mean a listing of all share types and the aggregate sum of shares associated to any natural persons, whether considered owners or investors.
<input type="checkbox"/>	A fully diluted capitalization table must sum to one hundred percent (100%) of all shares issued and outstanding;
<input type="checkbox"/>	A fully diluted capitalization table must list all share types and the aggregate sum of shares associated to any natural person as of a date no less than 7 calendar days prior to the date of the applicant's submission of its application for certification or renewal;
<input type="checkbox"/>	A fully diluted capitalization table must list only natural persons as owners and investors;
<input type="checkbox"/>	Provide all contractual relationships to change the control of the entity holding the certification, or to change its management, owners or investors, whether executed or not executed. Executed contractual relationships must be provided to the department prior to the approval.
<input type="checkbox"/>	Public companies are not exempt from any requirements in subsection (g) and must include additional documentation identifying all owners and investors that are considered Non-Objecting Beneficial Owners ("NOBOs").
<input type="checkbox"/>	A list of all owners, officers, board members, and managers that includes the date, within the calendar year prior to submission of the application, of the level 2 background screening required by this rule for each individual. Each owner, officer, board member, and manager shall go to the Florida Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such time, shall give to FDLE or the FDLE-approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF MEDICAL MARIJUANA USE).