

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



**APPLICATION AND INSTRUCTIONS FOR
CERTIFIED MARIJUANA TESTING LABORATORY CERTIFICATION**

SECTION 1: INTRODUCTION

This Application and Instructions for Certified Marijuana Testing Laboratory Certification (application) is designed to collect the information necessary to process and complete your application in a timely manner. Your assistance in providing all required information will help the Florida Department of Health's Office of Medical Marijuana Use (OMMU) process your application as soon as possible.

Please read these instructions carefully and fully before submitting your application and application fee. Questions regarding your application may be emailed to the OMMU at OMMULabs@flhealth.gov. Emails are generally responded to within 48 hours during normal business hours.

SECTION 2: THE APPLICATION PROCESS

For an application to be considered for approval by the OMMU, you must submit a complete application form and the application fee set forth herein. Upon receipt of your application and fee, the OMMU will review the application to ensure that all required written materials are included. When your application arrives, your application fee will be deposited. The application fee must clear the OMMU account in order for the application to be deemed complete.

If your application contains any apparent errors or omissions, the OMMU will notify you in writing and request any additional information required. The request for additional information will include a deadline for submitting the information identified by the OMMU. If the information requested is timely received, your application will be deemed complete and ready for evaluation.

SECTION 3: PREPARING AND SUBMITTING AN APPLICATION

Generally

Applications should provide a straightforward, concise description of the information or materials requested. Within the application, Applicants shall not include or apply any conditions or exceptions to any statutory or rule requirements.

It is solely the Applicant's responsibility to ensure that the application and any additional information is supplied timely and completely to the OMMU. Applications delivered by hand must be delivered to the physical address listed below. Applications that are shipped or mailed must be sent to the mailing address listed below.

Physical Address:

Florida Department of Health
Office of the General Counsel
ATTN: Agency Clerk
2585 Merchants Row Blvd., Suite 110
Tallahassee, Florida 32399

Mailing Address:

Florida Department of Health
Office of the General Counsel
ATTN: Agency Clerk
4052 Bald Cypress Way, Bin A-02
Tallahassee, Florida 32399

Format of Application

The application must be bound in a three-ring notebook with tabbed dividers labeled as follows:

Tab A – Form I – Applicant General Information

Tab B – Declaration of Exempt Information

Tab C – Accreditations and Certifications

Tab D – Proficiency Testing

Tab E – Personnel

Tab F – Background Screenings

Tab G – Infrastructure and Security

Tab H – Operations and Accountability

Tab I – Ownership

Tab J – Form II – Attestation of Compliance

A complete copy of the application in PDF format must be submitted on a USB flash drive together with the application hardcopy. The PDF copy must be identical to the original hardcopy version of the application. If there are any discrepancies between the original hardcopy and PDF version, the original hardcopy will control.

A redacted copy of the application with the statutory basis for each exemption clearly identified, as described in Tab B, below, must be included on the USB flash drive.

The application fee, in the amount of \$62,945.25 must be in the form of a cashier's check payable to "Florida Department of Health," and enclosed in an envelope.

Tab A – Form I Applicant General Information

Complete each section in Form I and include the completed form behind Tab A in your notebook.

Tab B – Declaration of Exempt Information

All application materials and electronic and written communications pertaining to an application, whether sent from or received by the OMMU, are subject to the Florida Public Records Law. Approval or denial of an application does not affect the public record status of the materials. Unless exempted by law, all public records are subject to public inspection and copying under Florida's Public Records Law, Chapter 119, Florida Statutes.

How to Claim Protection for Exempt Materials

If an Applicant considers any portion of the documents, data, or records submitted in its application to be a trade secret and/or otherwise exempt from public inspection or disclosure pursuant to Florida's Public Records Law, the Applicant must prominently and conspicuously mark all such information in the application as "Confidential – Exempt from Public Disclosure." The Applicant must submit a brief, written description of the grounds for claiming an exemption from the Public Records Law, including the specific statutory citation for such exemption.

An Applicant must also provide the OMMU with a separate, electronic, redacted copy of its application, redacting all data or information claimed to be exempt from public disclosure. The file name of the electronic, redacted copy must contain the name of the Applicant and "Redacted Copy." The first page of the electronic, redacted copy and each page on which information is redacted must prominently display the phrase "Redacted Copy." Except for the redactions, the redacted copy must be an exact duplicate of the original, unredacted application. The redacted copy of the application must be submitted simultaneously with the original, unredacted application.

As a matter of law, if an Applicant fails to mark any materials submitted to the OMMU as exempt from public disclosure, the Applicant waives the exemption under Chapter 119, Florida Statutes. Applicants exclusively bear the burden of complying with this section to ensure their exempt information is appropriately marked.

Tab C – Accreditations and Certifications

Behind Tab C, the Applicant must include:

- 1) Documentation to establish that the Applicant currently possesses ISO/IEC 17025:2017 accreditation in each Testing Field, identified in Florida Administrative Code Rule 64ER20-14(4)(a), for which the Applicant intends to test.
- 2) All materials and documents from the Applicant's most recent ISO/IEC 17025:2017 audit.
- 3) Documentation identifying the entity or person that awarded the ISO/IEC 17025:2017 accreditation, to include documentation evidencing recognition of that entity or person by the International Laboratory Accreditation Cooperation (ILAC); and
- 4) The initial certification report or the most recent audit report from an ILAC accredited auditing body.

Tab D – Proficiency Testing

Behind Tab D, the Applicant must include documentation evidencing satisfactory results on two of the three most recent proficiency tests administered by an ISO/IEC 17043:2010 accredited body for each Testing Field within a Matrix Group, identified in Florida Administrative Code Rule 64ER20-14(4)(b), for which the Applicant intends to test.

Tab E – Personnel

Behind Tab E, the Applicant must include:

- 1) An organizational chart illustrating the supervisory structure of the Testing Facility for which certification is sought. The chart must include the identities of all Managers and supervisors of personnel;
- 2) A narrative clearly describing the duties and responsibilities of each position listed in the organizational chart;
- 3) Documentation evidencing that the Laboratory Director meets the following requirements:
 - a. Only oversees one of the Applicant's physically independent CMTLs;
 - b. Is 21 years of age or older;
 - c. Holds a bachelor's degree in a natural science, including, but not be limited to, biology, chemistry, physics, engineering, or environmental sciences, or holds a current license as a Clinical Laboratory Personnel, as defined in section 483.803, F.S., from the Florida Board of Clinical Laboratory Personnel;
 - d. Has been provided specific training by the Applicant on the Applicant's minimum requirements for sampling and Standard Operating Procedures for sampling and security; and
 - e. Has a minimum of three (3) years of experience in an ISO, CAP, TNI, or similarly accredited laboratory environment.
- 4) Documentation evidencing that each Analyst meets the following requirements:
 - a. Is 21 years of age or older;

- b. Holds a bachelor's degree in a natural science, including, but not be limited to, biology, chemistry, physics, engineering, or environmental sciences, or holds a current license as a Clinical Laboratory Personnel, as defined in section 483.803, F.S., from the Florida Board of Clinical Laboratory Personnel; and
 - c. Has been provided specific training by the Applicant on the Applicant's minimum requirements for sampling and Standard Operating Procedures for sampling and security.
- 5) Documentation evidencing that each Sampler meets the following requirements:
- a. Is 21 years of age or older;
 - b. Has a high school diploma from a state-approved and accredited public or private school, or its equivalent; and
 - c. Has been provided specific training by the Applicant on the Applicant's minimum requirements for sampling and the Applicant's Standard Operating Procedures for sampling and sample security.
- 6) Documentation evidencing that each Employee meets the following requirements:
- a. Is 21 years of age or older; and
 - b. Has a high school diploma from a state-approved and accredited public or private school, or its equivalent.

Tab F – Background Screening

To be eligible for certification, all Owners, Managers, and Employees of the Applicant—including Samplers, Analysts, and Laboratory Directors—must successfully pass a level 2 background screening pursuant to section 435.04, F.S., and must not have 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. The procedures for background screening are set forth in the CMTL Background Screening rule.

Behind Tab F, the Applicant must provide the following information:

- 1) A complete list of the Applicant's prospective Owners, Managers, and Employees, as those terms are defined by CMTL rules;
- 2) For each identified Owner, Manager, and Employee, a copy of Form DH8023-OMMU-01/2020, "CMTL Waiver Agreement and Statement" which is available at: <https://knowthefactsmmj.com/rules-and-regulations/> and must be completed and signed by the prospective Owner, Manager, or Employee.

An Application will not be deemed complete until the OMMU receives a background screening report for all identified Owners, Managers, and Employees.

Tab G – Infrastructure and Security

Behind Tab G, the Applicant must include:

- 1) A floor plan identifying the location of all secure storage areas and security cameras;
- 2) The make, model, VIN number, license plate number and proof of registration and insurance for all vehicles that will be used to transport marijuana; and
- 3) A detailed plan that addresses all infrastructure and security requirements contained in Florida Administrative Code Rule 64ER20-14(4)(d).

Tab H – Operations and Accountability

Behind Tab H, the Applicant must submit Standard Operating Procedures that comply with the requirements of Florida Administrative Code Rule 64ER20-14(4)(e).

Tab I – Ownership

Applicants must provide sufficient documentation to the OMMU to provide reasonable assurance that any person or entity seeking certification as a CMTL is not owned and/or controlled by an MMTC.

Behind Tab I, an Applicant must provide:

- 1) A fully diluted capitalization table as required by Florida Administrative Code Rule 64ER20-14(4)(g). The 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 this application.
- 2) Any contract(s), the effect of which is to change the Control of the entity holding the certification, or to change its Management, Owners or Investors, whether executed or not executed.

Tab J – Attestation of Accuracy, Compliance, and Familiarity with the Law

Complete and sign Form II and include the completed form behind Tab J of your notebook.

FORM I

Applicant General Information

REGISTERED BUSINESS NAME			
DOING BUSINESS AS			
EMAIL ADDRESS OF BUSINESS FOR RECEIPT OF ALL DEPARTMENT CORRESPONDENCE			
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			

FORM II

Attestation of Accuracy, Compliance, and Familiarity with the Law

I do hereby attest that the Applicant is in compliance with all representations made to the Florida Department of Health, Office of Medical Marijuana Use, in this Application and Instructions for Certified Marijuana Testing Laboratory Certification. In addition, I further attest that I have read, am familiar with, and will comply with all relevant provisions of sections 381.986 and 381.988, Florida Statutes, and the Certified Marijuana Testing Laboratory rules adopted pursuant thereto.

Signature of Applicant's Authorized Representative

Date

Name of Applicant's Authorized Representative (print or type)

Name of Applicant/Entity