

CERTIFIED MARIJUANA TESTING LABORATORY (CMTL)

Renewal Application Instructions, Requirements, and Forms

OMMU Office of **MEDICAL**
MARIJUANA Use

Florida's Official Source for Responsible Use.

Florida
HEALTH

PART 1: INTRODUCTION	3
PART 2: THE RENEWAL PROCESS.....	3
Section 2.1 General Overview	3
Section 2.2 Renewal Application Submission	3
Section 2.3 Public Records and Applicant’s Confidential Information	4
Subsection 2.3.1 – Public Records	4
Subsection 2.3.2 – Applications Are Public Record	4
Subsection 2.3.3 – How to Claim Protection for Exempt Materials	4
Subsection 2.3.4 – Public Records Requests.....	5
Subsection 2.3.5 – Department Not Obligated to Agree with a Renewal Applicant’s Claim.	5
PART 3: PREPARING AND SUBMITTING A RENEWAL APPLICATION	5
Section 3.1 Submittal of Renewal Application	5
Section 3.2 Format of Renewal Application	6
PART 4: CONTENT OF RENEWAL APPLICATION	7
Section 4.1 General Information and Renewal Application Fee.....	7
Section 4.2 Declaration of Exempt Information	7
Section 4.3 Accreditations.....	8
Section 4.4 Proficiency Testing	8
Section 4.5 Personnel	8
Section 4.6 Infrastructure and Security	9
Section 4.7 Operations and Accountability.....	9
Section 4.8 Level 2 Background Screening.....	9
Section 4.9 Capitalization Tables, Change of Control, and Related Entities.....	10
Section 4.10 Acknowledgement of Accuracy	10
PART 5: APPARENT ERRORS AND OMISSIONS	11
PART 6: APPROVAL OR DENIAL OF RENEWAL APPLICATION	11
FORM 1: RENEWAL APPLICANT GENERAL INFORMATION	12
FORM 2: RENEWAL APPLICANT’S ACKNOWLEDGMENT AND STATEMENT OF UNDERSTANDING	13

PART 1: INTRODUCTION

This *Renewal Application Instructions, Requirements, and Forms* (Renewal Instructions) document is designed to collect the information necessary to process and complete your certification renewal in a timely manner. Your assistance in providing all required information will help the Florida Department of Health's Office of Medical Marijuana Use (the Department) process your renewal application as soon as possible.

Please read these Renewal Instructions carefully and completely before submitting your renewal application. Questions regarding your renewal application may be emailed to the Department at OMMUlabs@flhealth.gov.

Specific definitions are set forth in section 381.986, Florida Statutes (F.S.), and the Department's rules (Chapter 64-4, Florida Administrative Code (F.A.C.)) and emergency rules (located at <https://knowthefactsmmj.com/rules-and-regulations/>). Those definitions apply to these Renewal Instructions.

A CMTL must, at all times of certification, maintain compliance with sections 381.986, 381.988, F.S., and Department rules.

PART 2: THE RENEWAL PROCESS

Section 2.1 General Overview

For your renewal application to be considered for approval by the Department, you must submit a complete certification renewal application and the renewal fee. Upon receipt of your renewal application, the Department will review the renewal application to ensure that all required materials and information are included. When your renewal application arrives, your renewal fee will be deposited. If your renewal application contains apparent errors or omissions, you will be notified in writing of the apparent errors or omissions, or if additional information is needed, and you will be afforded an opportunity to timely correct the errors or omissions and supply additional information, as requested. *See* Part 5 below.

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

Section 2.2 Renewal Application Submission

It is solely the renewal applicant's responsibility to ensure that the renewal application and any additional information is timely delivered to the Department. A renewal application will be considered delivered when it is physically tendered to the Agency Clerk. **Applications submitted by facsimile, email, or other forms of electronic delivery will not be accepted.** Only the Agency Clerk is authorized to accept renewal applications. The Agency Clerk will date and time-

stamp Form 1 (Renewal Applicant General Information) of your renewal application as of the date and time the renewal application is delivered to the Agency Clerk.

Use of U.S. mail for the submission of a renewal application will result in delivery of the application to the Department's central mailroom. Delivery to the central mailroom will not constitute delivery of the renewal application to the Agency Clerk. If the renewal application is delivered to the central mailroom, the central mailroom staff will deliver the renewal application, along with other mail directed to the Agency Clerk, in the ordinary course of business, which may be several days after initial delivery to the mailroom. Timely delivery of a renewal application to the Department's Agency Clerk is exclusively the responsibility of the renewal applicant and the risk of non-delivery, delayed delivery, or delivery after the deadline will be borne exclusively by the renewal applicant.

The delivery address for renewal applications is as follows:

Agency Clerk
Florida Department of Health
2585 Merchants Row Blvd., Suite 110
Tallahassee, FL 32399

Section 2.3 Public Records and Applicant's Confidential Information

Subsection 2.3.1 – Public Records

All electronic and written communications pertaining to a CMTL renewal application, whether sent from or received by the Department, are subject to the Florida Public Records Law laid out in Chapter 119, F.S. Section 2.3.3 below addresses procedures for submission of a renewal application containing trade secret and other information an applicant contends is exempt from public inspection.

Subsection 2.3.2 – Applications Are Public Record

All renewal applications (and material and information contained therein) will be a public record subject to the provisions of Chapter 119, F.S. Approval or denial of a renewal application for licensure does not affect the public record status of the materials.

Subsection 2.3.3 – How to Claim Protection for Exempt Materials

If a renewal applicant considers any portion of renewal application-related documents, information, or records submitted to the Department to be a trade secret and/or otherwise exempt from public inspection or disclosure pursuant to Florida's Public Records Law, the renewal applicant should prominently and conspicuously mark all such information as "Confidential–Exempt from Public Disclosure." The renewal applicant should submit a brief, written description of the grounds for each exemption claimed under the Public Records Law, including the specific statutory citation for such exemption.

If a renewal applicant submits to the Department renewal application-related documents, information, or records that it believes to be a trade secret and/or otherwise exempt from public inspection or disclosure, the renewal applicant must also simultaneously provide the Department with a separate, electronic, redacted copy of the documents, information, or records, redacting all information claimed to be exempt from public disclosure. 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 material. This submission must be made simultaneously with the original document, information, or record.

Subsection 2.3.4 – Public Records Requests

Failure to provide a redacted copy of the renewal application at the time of submission, or failure to identify and redact information claimed as trade secret or otherwise exempt information, may result in the release of all renewal application-related information in response to a public records request unless the information is confidential or falls under another public records exemption. Renewal applicants exclusively bear the burden of ensuring exempt information is appropriately marked.

Subsection 2.3.5 – Department Not Obligated to Agree with a Renewal Applicant’s Claim

The Department is not obligated to agree with a renewal applicant’s claim of exemption, and by submitting a renewal application claiming an exemption from disclosure, the renewal applicant agrees to defend its claim that any or some portion of its renewal application is exempt from inspection and copying under Florida’s Public Records Law. Further, by submitting a renewal application claiming an exemption from disclosure, the renewal applicant agrees to protect, defend, indemnify, and hold harmless the Department for any and all claims and litigation (including litigation initiated by the Department), including attorney’s fees and costs, arising from or in any way relating to the renewal applicant’s assertion that the redacted portions of its renewal application are exempt from public disclosure under Chapter 119, F.S.

PART 3: PREPARING AND SUBMITTING A RENEWAL APPLICATION

Section 3.1 Submittal of Renewal Application

A renewal application must be submitted in a properly marked box or envelope containing the following:

- a. One electronic renewal application in Adobe Acrobat PDF format on a portable drive. The renewal application must be electronically **bookmarked** as provided in Section 3.2 below. Acceptable portable drives include a portable hard drive, USB flash drive,

and similar devices. The portable drive must have a USB connection and must be compatible with Microsoft operating systems. The PDF file containing the unredacted renewal application must be named in the following format: “*Renewal Applicant Name*” (e.g., “John Smith, Inc.”);

- b. Renewal applicants claiming protection for exempt materials must also submit one electronic, **redacted** renewal application, as described in Subsection 2.3.3. The redacted renewal application must be in PDF format and electronically **bookmarked** on a portable drive. The PDF file containing the redacted renewal application must be named in the following format: “*Renewal Applicant Name – Redacted*” (e.g., “John Smith, Inc. – Redacted”);
- c. A hardcopy of completed Form 1 (Renewal Applicant General Information) for the Agency Clerk to stamp as provided in Section 2.2 above; and
- d. A cashier’s check made payable to “Florida Department of Health” for the required renewal application fee. Renewal application fees are non-refundable.

The face of each box or envelope submitted must be addressed to the attention of the Agency Clerk and indicate the Agency Clerk’s address, as provided in Section 2.2 above. In addition, the face of each box or envelope must state “[*Applicant Name*] – *CMTL Renewal Application*.” Renewal applicants desiring to retain a hardcopy of the time-stamped Form 1 should provide an extra hardcopy of Form 1 for the Agency Clerk to stamp.

Section 3.2 Format of Renewal Application

Renewal applicants must submit a renewal application that contains the information and materials requested in Part 4 of these Renewal Instructions and arranged in the following format and order. Applications must be submitted in Adobe Acrobat PDF format and electronically bookmarked by section in the order below using the Adobe bookmarking function. Applicants are encouraged to visit www.adobe.com for information on the Adobe bookmarking function.

The electronic bookmark’s name must match the names below (for example, “*Section 4.1 – Form 1: Renewal Applicant General information*”).

- Section 4.1 – General Information and Renewal Application Fee
- Section 4.2 – Declaration of Exempt Information
- Section 4.3 – Accreditations
- Section 4.4 – Proficiency Testing
- Section 4.5 – Personnel

- Section 4.6 – Infrastructure and Security
- Section 4.7 – Operations and Accountability
- Section 4.8 – Level 2 Background Screening
- Section 4.9 – Capitalization Tables, Change of Control and Related Entities
- Section 4.10 – Acknowledgment of Accuracy

Renewal applicants must insert a page break between each electronically bookmarked section such that each section of the renewal application begins on a new page.

All narrative responses included in the application must be double spaced in Times New Roman, 12-point font, with one-inch margins, and set to 8½ by 11-inch paper size.

PART 4: CONTENT OF RENEWAL APPLICATION

Each of the following sections contain requests for information and documents to be provided by renewal applicants. Carefully review each and supply the requested information and documents. Renewal applicants must adhere to the formatting convention provided in Part 3 of the Renewal Instructions.

Section 4.1 General Information and Renewal Application Fee

Renewal applicants must complete each section in Form 1 (Renewal Applicant General Information) and provide the completed Form 1.

The email address provided for the renewal applicant on Form 1 will be the only email address to which the Department will send emails to the applicant and will be the only email address from which the Department will accept emails from the applicant.

Section 4.2 Declaration of Exempt Information

Renewal applicants must provide a listing of information that is claimed to be exempt from public disclosure. This listing shall identify each section of the renewal application that has been excluded from the Redacted Copy provided with the application, as described in Section 2.3 of these Renewal Instructions.

If a renewal applicant is not declaring any information as exempt, then it must include a statement to that effect.

Section 4.3 Accreditations

The renewal applicant must provide:

1. Documentation of the renewal applicant's most recent ISO/IEC 17025:2017 (revised March 2018) accreditation in each Testing Field, identified in Emergency Rule 64ER20-14(4)(a), for which the renewal applicant is certified to test.
2. The on-site assessment report, technical review matrix, and nonconformance report and responses from the renewal applicant's most recent ISO/IEC 17025:2017 (revised March 2018) audit.
3. Documentation identifying the entity or person that awarded the ISO/IEC 17025:2017 (revised March 2018) accreditation, to include documentation evidencing recognition of that entity or person by the International Laboratory Accreditation Cooperation (ILAC).
4. The most recent audit report from an ILAC accredited auditing body.

Section 4.4 Proficiency Testing

The renewal applicant must provide documentation evidencing satisfactory results required by Emergency Rule 64ER20-14(4)(b), on the most recent proficiency test administered by an ISO/IEC 17043:2010 accredited body for each Testing Field within a Matrix Group, identified in Emergency Rule 64ER20-14(4)(b), for which the renewal applicant currently tests. The proficiency test must have been administered in the six months immediately preceding the renewal application submission date.

Section 4.5 Personnel

The renewal applicant must provide a complete, alphabetical listing of all current Employees, Owners and Managers, as those terms are defined in Emergency Rule 64ER20-1, together with all of the following information for each individual:

1. An organizational chart illustrating the supervisory structure of the Testing Facility for which certification renewal 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 requirements of Emergency Rule 64ER20-14(4)(c);
4. Documentation evidencing that each Analyst meets the requirements of Emergency Rule 64ER20-14(4)(c);
5. Documentation evidencing that each Sampler meets the requirements of Emergency Rule 64ER20-14(4)(c); and
6. Documentation evidencing that each Employee meets the requirements of Emergency Rule 64ER20-14(4)(c).

Section 4.6 Infrastructure and Security

The renewal applicant must provide:

1. A current floor plan identifying the location of all secure storage areas and security cameras;
2. A list containing the current make, model, VIN number, license plate number and proof of registration and insurance for all vehicles used to transport marijuana; and
3. A current copy of the renewal applicant's written Standard Operating Procedures (SOPs) that address all infrastructure and security requirements contained in Emergency Rule 64ER20-14(4)(d).

Section 4.7 Operations and Accountability

The renewal applicant must provide:

1. A current copy of the renewal applicant's written SOPs addressing Quality Assurance and Quality Control procedures that address all requirements contained in Emergency Rule 64ER20-14(4)(e).
2. An audit report pursuant to Emergency Rule 64ER20-14(4)(e)3. performed within the 90-day period prior to submission of the renewal application.

Section 4.8 Level 2 Background Screening

Renewal applicants must provide information that will allow the Department to confirm that the renewal applicant's current Owners and Managers, as those terms are defined in Emergency Rule 64ER20-1, have passed a level 2 background screening. To this end, renewal applicants must provide the following:

1. An alphabetical listing of all current Owners and Managers of the renewal applicant, as those terms are defined in Emergency Rule 64ER20-1.
2. For each identified individual (whether an Owner or Manager) include the following:
 - a. Date of birth
 - b. Social Security number
 - c. Hire date
 - d. Position/job title

The information supplied by the renewal applicant in Section 4.8 of the renewal application will be compared to the data in the Applicant Fingerprint Retention and Notification Program authorized by section 943.05(2)(b), Florida Statutes, and established by the Florida Department of Law Enforcement, as provided in Rule 11C-6.010, F.A.C.

If for any reason an Owner or Manager does not have current data in the Applicant Fingerprint Retention and Notification Program, then the Owner or Manager must undertake the background

screening process provided in the Department’s CMTL Background Screening rule prior to submission of the renewal application.

Section 4.9 Capitalization Tables, Change of Control, and Related Entities

Renewal applicants must provide sufficient documentation to the Department to provide reasonable assurance that the renewal applicant seeking approval is not owned and/or controlled by an MMTC. To this end, renewal applicants with ownership attributable to an entity must provide the following:

1. A fully diluted capitalization table listing all share types and the aggregate sum of shares associated with or flowing to any natural persons, whether considered owners or investors. In addition, identify the natural person owners and natural person beneficiaries of all entities listed on the capitalization table. For purposes of ownership attribution, please provide the nature of the familial relationship, if any, between the natural person owners and natural person beneficiaries identified on the capitalization table. *See* Emergency Rule 64ER20-1 for the applicable definitions and attribution of ownership.
2. If the renewal applicant is a publicly traded corporation, the capitalization table must:
 - a. List all share types and aggregate sum of shares associated to any officers and directors;
 - b. List the share types and aggregate sum of shares associated to any investor who acquired shares during the issuance of a private placement offering or any other type of offering in which shares were acquired by pre-selected investors and institutions (private equity investors), as opposed to shares acquired on the open market by public investors; and
 - c. List the share types and aggregate sum of shares associated to the entirety of public investors (“shares held in public float”), as opposed to company officers, directors, private equity investors, or any other shareholder considered an owner.
3. All agreements concerning control of the renewal applicant, or change of control (if any), including changes to management, owners, partners, or investors, regardless of whether the change is contingent or vested; and
4. Identify all entities related to the renewal applicant (if any), including parent companies, subsidiary companies, sister companies, and any other affiliated companies and provide all documents of these related entities that pertain to the ownership or control of the renewal applicant.

Section 4.10 Acknowledgement of Accuracy

Renewal applicants must complete each section in Form 2 (Acknowledgment of Accuracy, Compliance, and Familiarity with the Law) and include the completed form behind Section 4.10 of your renewal application.

PART 5: APPARENT ERRORS AND OMISSIONS

If your renewal application contains any apparent errors or omissions, the Department will notify you in writing and afford you an opportunity to correct the errors or omissions and supply additional information, responses, or materials (“Errors and Omissions Letter”). The Department’s Errors and Omissions Letter will be sent to renewal applicants by email at the designated email address supplied on Form 1 and included behind Section 4.1 (Renewal Applicant General Information). It is the renewal applicant’s responsibility to monitor its email account and to ensure that all filters and spam blockers do not block, quarantine, or otherwise delay delivery or receipt of emails from OMMUlabs@flhealth.gov. Delays caused by such blocking and quarantining will not suffice as good cause for additional time to respond to the Department’s Errors and Omissions Letter.

The Department must receive the additional information, responses, or materials requested in the Errors and Omissions Letter within 14 calendar days of the date on which the Department emails the Errors and Omissions Letter. However, this deadline may be extended upon request and for good cause shown. Responses to Department’s Errors and Omissions Letter must be delivered to the Agency Clerk by 5:00 p.m. on the deadline. The delivery address for responses to the Department’s Errors and Omissions Letters is as follows:

Agency Clerk
Florida Department of Health
2585 Merchants Row Blvd., Suite 110
Tallahassee, FL 32399

Timely delivery to the Department’s Agency Clerk is exclusively the responsibility of the applicant and the risk of non-delivery, delayed delivery, or delivery after the deadline will be borne exclusively by the applicant.

Failure to provide the information and materials requested in the Department’s Errors and Omissions Letter may result in the denial of your renewal application.

PART 6: APPROVAL OR DENIAL OF RENEWAL APPLICATION

The Department will issue the renewal applicant written notice by letter stating whether the Department intends to grant or deny the renewal application. The letter will be issued via certified mail.

FORM 1: RENEWAL APPLICANT GENERAL INFORMATION

Renewal Applicant Information				
Applicant Name				
Fictitious Name, if any				
Street Address of Testing Facility				
City	Apt/Ste #	State	ZIP Code	Country
Mailing Address (if different)				
City	Apt/Ste #	State	ZIP Code	Country

Contact Information		
First Name	Last Name	Middle Initial
Telephone Number	Designated Email (for Department/Applicant Communications)	

FORM 2: RENEWAL APPLICANT’S ACKNOWLEDGMENT AND STATEMENT OF UNDERSTANDING

I, _____, the undersigned representative, hereby represent and warrant that I am authorized to submit this renewal application on behalf of the applicant listed on the renewal application (the Applicant) and to attest to the following on behalf of the Applicant.

- All information included in the renewal application is true and correct. Applicant understands that the Department will rely on such information, and that any material misrepresentation in this renewal application is grounds for certification denial. Further, Applicant understands that if the Applicant knowingly makes a false statement in writing with the intent to mislead a public servant in the performance of his or her official duty, the Applicant may be found guilty of a misdemeanor of the second degree, punishable as provided in sections 775.082 or 775.083, F.S.
- At the time of this renewal application, the Applicant is in compliance with all representations made to the Department for certification as a Certified Testing Laboratory, including representations in the renewal application and the initial application, except as modified by application amendments or otherwise approved by the Department, and will remain in compliance during the effective certification period.
- Notwithstanding the contents of the renewal application, upon certification renewal, Applicant agrees to abide by, and be bound to, all the requirements of section 381.986, F.S., section 381.988, F.S., and all Department rules relating to CMTLs.
- No currently licensed MMTC owns or controls the Applicant.
- Applicant understands and agrees that if the Department determines at any point after certification that the renewal application contained a material misrepresentation, then the certification will be revoked.

Applicant Name (Printed): _____

Applicant Signature: _____

Position of Signatory: _____