

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



**APPLICATION INSTRUCTIONS FOR
MARIJUANA TESTING LABORATORY CERTIFICATE**

EFFECTIVE _____ 2019

SECTION 1: INTRODUCTION

The information in this packet has been designed to provide the essential information required to complete and process your application. Your assistance in providing all required information will enable the Florida Department of Health's Office of Medical Marijuana Use (OMMU) to process your application as quickly as possible. You are encouraged to apply as early as possible to avoid processing delays caused by large volumes of applicants.

A complete application and submission of the application fee is required before your application will be reviewed and evaluated. Please read these instructions carefully and fully before submitting your application. It is recommended that you retain a copy of your completed application and all other materials submitted to the OMMU. Completed application and fees must be submitted to the address noted in the instructions and on the application form.

If you need to communicate with the OMMU staff, you are encouraged to email the OMMU at _____, or you may call us at (850) _____. Phone calls are typically returned within 1 business day and emails are responded to within 2 business days. Normal business hours for the OMMU are Monday through Friday between the hours of 8 AM and 5PM.

SECTION 2: BACKGROUND

Marijuana testing laboratories are tasked with ensuring that all products available for qualified patients are safe for human consumption, and all labels of cannabinoid concentrations are accurate.

As a reminder, all certified marijuana testing laboratories must adhere to the requirements of sections 381.986(8)(d), 381.986(8)(e)11. d., 381.986(8)(g), and 381.988, F.S., and related rules.

SECTION 3: THE APPLICATION PROCESS

For an application to be considered for approval by OMMU, a complete application form and application fee must be submitted. For instructions regarding the contents of the application, see Section 4 below.

Upon receipt of an application and fee, OMMU will review the application to ensure that all required written materials are included. Application fees will be deposited upon receipt of a complete completed application. Fees must clear the OMMU account before staff review will begin. An application will not be processed if payment does not clear the OMMU account. Application fee must be in the form of a certified or cashier's check.

The OMMU will acknowledge receipt of the application within 30 days of receiving an application and fees. If the application contains all the required written materials, the applicant will receive notification that an inspector will be in contact to schedule a facility inspection appointment. The information collected during the facility inspection will become part of the application and consequently no application will be deemed complete until an inspection occurs.

In the event a submitted application does not contain all the required written information and materials, the applicant will be provided in writing a list of all missing required information or materials along with a deadline for submitting the missing information or materials. Once those materials or information are received by OMMU, a facility inspection appointment can be scheduled.

All applications will be approved or denied within 90 days of the application being deemed complete by OMMU. Therefore, failure to submit timely all required information and materials may delay the inspection, and in turn delay the decision on the application.

SECTION 4 – 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 or materials is supplied to the OMMU timely and completely. Applications must be submitted to:

Florida Department of Health
ATTN: Office of Medical Marijuana Use
4052 Bald Cypress Way, Bin M-01
Tallahassee, Florida

Format of Application

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

Tab A – Form _____ – Applicant General Information and Application Fee

Tab B – Declaration of Exempt Information

Tab C – Accreditations and Certifications

Tab D – Proficiency Testing

Tab E – Personnel

Tab F – Infrastructure and Security

Tab G – Operations and Accountability

Tab H – Ownership

In addition, 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 Department will make decisions based off the original hardcopy.

Tab A Form _____ – Applicant General Information and Application Fee

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

Additionally, enclose in a manila envelope a cashier's check or money order made payable to "Florida Department of Health."

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 Department, 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. Any claim of trade secret exemption for any information contained in application will be waived upon submission of the application to the OMMU, unless the claimed trade secret information is submitted in accordance with these instructions.

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 exemption from the Public Records Law, including the specific statutory citation for such exemption.

A vendor must also simultaneously 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, un-redacted application. This submission must be made simultaneously with the original application.

As a matter of law, if an applicant fails to mark any materials submitted to the Department 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.

The OMMU is not obligated to agree with a vendor's claim of exemption.

If you are not declaring any information as exempt, then include a statement to that effect behind Tab B.

Tab C Accreditations and Certifications

The applicant must include documentation to establish that the applicant itself currently possesses ISO/IEC 17025:2017 accreditation.

Additionally, the applicant must include:

- 1) All materials and documents submitted to_____for the most recent ISO/IEC 17025:2017 audit.
- 2) Documentation identifying the entity or person that awarded the ISO/IEC 17025:2017 accreditation, to include recognition by the International Laboratory Accreditation Cooperation (ILAC);
- 3) Initial certification report or the most recent audit report from an ILAC accredited auditing body.

Tab D Proficiency Testing

For each of the following testing fields within each matrix group, the applicant must provide documentation evidencing satisfactory results for the two most recent proficiency tests administered by an ISO/IEC 17043:2010 accredited body:

1. Usable whole flower marijuana

Microbiology
Mycotoxins
Heavy metals
Pesticides
Water activity
Moisture
Cannabinoid profile

2. Derivative products

Microbiology
Mycotoxins
Residual solvents
Heavy metals
Pesticides
Water activity
Moisture
Cannabinoid profile

3. Edibles

Microbiology
Mycotoxins
Residual solvents
Heavy metals
Pesticides
Water activity
Moisture
Cannabinoid profile

Tab E Personnel

Behind Tab E, the applicant must include: 1) an organizational chart illustrating the supervisory structure of each physically independent testing facility operated by the applicant for which certification is sought. The chart must include the identities of all laboratory directors, analysts, samplers, and employees. 2) For each position, the applicant must also include 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 testing facilities;
- b. Is 21 years of age or older;
- c. 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;
- d. 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 license from the Florida Board of Clinical Laboratory Personnel;
- e. A minimum of three (3) years of experience in a regulated laboratory environment sufficient for any accreditation required by this rule.

4) Provide documentation evidencing that each analyst meets the following requirements:

- a. Is 21 years of age or older;

- b. 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;
 - c. 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;
 - d. Has been provided specific training on the applicant's standard operating procedures for sampling and security.
- 5) Provide documentation evidencing that each sampler meets the following requirements:
- a. Is 21 years of age or older;
 - b. 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;
 - c. Has been provided specific training on the minimum requirements for sampling and the applicant's standard operating procedures for sampling and security.
- 6) Provide documentation evidencing that each employee meets the following requirements:
- a. Is 21 years of age or older;
 - b. 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;

Tab F Infrastructure and Security

Behind Tab F, the applicant must include:

- 1) A floor plan including the location of all secure storage areas.
- 2) A detailed plan for all security measures to comply with Rule 64-4.301 (6)(e).

Tab G Operations and Accountability

Behind Tab G the applicant must submit operating procedures that comply with the requirements of 64-4.301(6)(f).

Tab H 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.

Behind Tab H, provide:

1) A fully diluted capitalization table as required by 64-4.301(6)(h). Fully diluted capitalization table is a listing of all share types and the aggregate sum of shares associated to any natural persons, whether considered owners or investors.

2) 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.

3) 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).

Tab I Business Agreements

Behind Tab I, the applicant must submit a copy of all current business agreements between the Applicant and any Medical Marijuana Treatment Center that comply with the requirements of 64-4.301(7).

FORM ____

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			