NEW MEXICO DEPARTMENT OF HEALTH

Medical Cannabis Program Laboratory Application Cover Page:

Business Name, DBA: _____

Date application submitted: _____ Owner / Applicant: _____

Telephone: _____ Email address: _____

Select the purpose of this application:

☐ Laboratory, new application
☐ Laboratory, renewal application

Application and Fees (Due Dates and Costs)

Laboratory applicants shall submit an authorized application form to the program with each initial application and at the time of the Laboratory's renewal, together with a fee of two thousand, two hundred dollars and zero cents ($2,200.00) payable to the Medical Cannabis Program; this fee is non-refundable. An approved Laboratory shall apply for renewal annually, no later than at least 60 days prior to expiration. There will be no extensions granted for the submittal deadline.

Check #: _____ Amount: _____

or

Money Order #: _____ Amount: _____

Submit Application electronically on a non-returnable USB drive *See Note

Submit electronic USB drive to the following address:

New Mexico Department of Health
5301 Central Ave. NE, Suite 204
Albuquerque, NM 87108

Note: Incomplete applications will not be processed. For the application to be considered complete, all requested documents must be submitted together as a compendium that includes the cover page.

MCP Laboratory Application

Year: _____

Applicant Information

Laboratory Name
DBA Business
Name: _____ Date: _____

Address: _____
Street Address *Suite/Unit #*

_____
City *State* *ZIP Code*

Mailing Address: _____ Phone: _____
_____ Phone: _____
_____ Phone: _____

Email: _____
Print name of laboratory Owner: _____
Anticipated open date: _____

Disclaimer: The medical cannabis program (MCP) may deny, withdraw or suspend approval of a laboratory application, for any violation of 7.34.4 NMAC, to include failed proficiency testing, denied departmental access to premises or materials and to comply with any standard, procedure or protocol developed, submitted or maintained. In the event of failed testing results, the department may require additional tests or remedial actions to be taken. Submission of this laboratory application, does not guarantee approval. Laboratory may not begin handling medical cannabis products, until the application is approved by the MCP.

Laboratory applications must be submitted annually; approvals are good for 1 year from the date of approval. Applications will not be considered at the address of a private residence/dwelling and location must be zoned appropriately. The MCP may conduct periodic unannounced evaluations/inspections at any time during the approval period. Continued demonstration of capability of all analysis conducted may be required during the licensure period.

Laboratory employee identification cards are the property of the MCP and must be immediately surrendered in the event of employee suspension, termination, license revocation or upon demand of the department. All laboratory test results conducted on cannabis or cannabis derived products, shall be retained for a period of not less than two (2) years and any testing records shall be made readily available upon departmental request.

The following are the items needed to satisfy a complete laboratory application for the testing of medical cannabis and medical cannabis derived products. Each listed item must be submitted in electronic format in order for the application to be considered complete. Check each box once each item is satisfied and is

ready to submit to MCP; submit items in the order they are listed. An electronic jump drive containing the application will need to be provided with non-refundable application fee at time of submittal.

***NOTE: Due to the current COVID -19 pandemic, applications will only be received electronically. An appointment can be made to provide the non-refundable fee at time of submittal.**

Testing categories: A laboratory applicant must be able to provide testing capabilities in the all of the following categories:

1). Mycotoxin analysis;

2). Microbiological contaminant analysis;

3). Solvent residue analysis;

4). Potency analysis (Cannabinoid content);

5). Pesticide analysis;

6). Heavy Metals analysis;

For the application to be considered complete, the applicant must submit all the following items as per 7.34.4.17 NMAC:

☐ 1. Standard operating procedures to be followed by the laboratory, including but not limited to policies and procedures to be used in performing analysis of samples:

Standard Operating Procedure (SOP) complete with, but not limited to:

a. Descriptions of Purpose, Scope, Responsibilities, References, Records/Data handling, Results reporting, Acceptable sample types/conditions.

b. A definition of quality controls as well as quality assurance measures (acceptable ranges and procedures if controls are out of range and documentation of these events).

c. A list of chemical reagents, analytical reference standards, instrumentation, GC or LC column, and extraction equipment used in the method.

d. The formulations of the controls and their storage and assignment of expiration dates.

e. A detailed description of the calibration of the instrument.

f. A detailed description of the extraction procedure.

g. A detailed description of how an instrument response is converted into a result for reporting.

h. A detailed description of how samples are disposed.

i. Safety (how are samples and chemicals handled).

☐ 2. A description of the type of tests to be conducted by the laboratory applicant, which may include, but are not limited to, testing for microbiological contaminants, mycotoxins, residual solvents, potency analysis, water content analysis, heavy metals, and pesticides.

☐ 3. Quality control criteria for the test(s) that the applicant intends to conduct.

☐ 4. Evidence that validates the accuracy of the test(s) to be conducted by the laboratory applicant as performed in the applicant's laboratory (Proficiency testing):

Proficiency Testing /Results:

A laboratory must provide the results and the evaluation report of a Proficiency Test (PT) for the method analytes. Proficiency testing must be performed annually. When there may not be a PT available for the target analytes, the laboratory can be given some leeway. A QC Check control made from analytical reference standards obtained from a second vendor different from the vendor who supplied the materials used to calibrate the instrument can be used in lieu of a PT.

a. A copy of the final test report.
b. Training documentation for all analysts that conduct proficiency test.
c. Employee information for each employee participating in proficiency test.

☐ 5. Proof of "Good Standing" with New Mexico Taxation and Revenue Department.

☐ 6. Proof of "Good Standing" with the New Mexico Secretary of State.

☐ 7. Copies of Articles of Incorporation and by–laws.

☐ 8. A list of all individuals or business entities having direct or indirect authority over the management or policies of the laboratory applicant.

☐ 9. A list of all persons or business entities having any ownership interest in any property used by the laboratory applicant, whether direct or indirect and whether the interest is in land, buildings or other material, including owners of any business entity that owns all or part of the land or building utilized.

☐ 10. A description of the facilities and equipment that shall be used for cannabis testing.

☐ 11. A description of how the laboratory will ensure and document "chain of custody" for samples that are held and tested at the approved laboratory, include a copy of the "chain of custody" document.

☐ 12. A general written security policy, to address at a minimum safety and security procedures.

☐ 13. Written attestation that no firearms will be allowed or used on any premises used by the approved laboratory.

☐ 14. A description of the methods and device or series of devices that shall be used to provide security

☐ 15. Copies of all training documents for each employee, which entail statements signed by employees indicating each topic discussed (include names and titles of trainers/presenters) that lists the date, time and location employees received training.

☐ 16. Copies of personnel records for every employee of the laboratory applicant, to include and application for employment, and records of all disciplinary actions taken.

☐ 17. Employee safety and security training materials signed by each employee at the time of hire, which reflects training in the proper use of adopted security measures, controls and specific procedural instructions which guide employees on how to respond to emergency situations, from minor infractions to robbery, accidents and any violent acts.

The MCP requires the following items be submitted, as per 7.34.4.17, 7.34.4.18:

☐ 18. Fire Marshal inspection
☐ 19. Current Business License Registration
☐ 20. Zoning information
☐ 21. Certificate of Occupancy for structure that the laboratory will operate in.
☐ 22. Documented proof of required initial and continuing demonstrations of capability, in accordance with this rule:

Proof of an Initial Demonstration of Capability (IDC), includes the following elements:

a. **Demonstration of method calibration -** The calibration range shall use at least five calibration points consisting of five different concentration levels of target compounds. The calibration range shall include a low calibration point equal to, or less, than the required minimum reporting level for each targeted compound. The calibration range shall include a calibration point equal to the action level for each targeted compound (mycotoxins and residual solvents). A laboratory or laboratory applicant shall provide the equation and the type of curve fit used for the calibration range, and the percent relative standard deviation or the goodness of fit. The percent relative standard deviation shall be less than twenty percent, or the goodness of fit (correlation coefficient) shall be 0.995 or better.

b. **Demonstration of method accuracy and precision -** A laboratory or laboratory applicant shall supply the quantitation data for five positive control samples analyzed by its testing method utilizing a median or mid-level calibration concentration. A laboratory or laboratory applicant shall calculate and provide the calculated mean (average) result and the standard deviation. The percent relative standard deviation shall be less than fifteen percent, and the mean shall be within fifteen percent of the expected concentration. For laboratories using GC-FID, GC-PID/FID, or GCMS platforms for residual solvents, the percent relative standard deviation may be within twenty percent, and the mean may be within twenty percent, of the expected concentration for the targeted compounds propane, n-butane, isobutane, and methanol**.**

c. **Demonstration of method detection limit -** A laboratory or laboratory applicant shall supply the quantitation data of seven low-level or minimum action level positive control samples. The concentration of these low-level positive control samples is set equal to the lowest calibration point the laboratory uses. These data are then used to calculate a standard deviation, which is then used to calculate method detection limit (MDL) using the following equation: (3.14267 x standard deviation = method detection limit). The calculated method detection limit for each targeted mycotoxin and residual solvent shall be less than the required method reporting level. For potency testing, quantitation values of all the seven low-level positive controls fall within fifty percent to one hundred and fifty percent of the expected concentration for the cannabinoids THC, THCA, CBD, and CDBA.

d. **Demonstration of low system background -** A laboratory or laboratory applicant shall supply the analytical data of at least three negative control samples that do not contain any mycotoxins, residual solvents, or cannabinoids. For mycotoxins and residual solvents, the quantitation values shall be less than the minimum detection limit or a non-detect. For potency testing, the quantitation values shall be less than one-third of the value of the method reporting level**.**

e. **Demonstration of analyte identification -** A laboratory that uses, and a laboratory applicant than intends to use, HPLC, GC-FID, or GC-PID/FID instrumentation shall supply analytical data where each targeted compound is analyzed as a single compound giving it its characteristic retention time. A laboratory that uses, and a laboratory applicant than intends to use, GCMS, LCMS, or LCMSMS instrumentation shall supply analytical data with the characteristic mass spectrum of each targeted compound.

☐ 23. Signed/Stamped Survey within 1 year of the application demonstrating proof that no buildings to be used by the applicant are located within 300 feet of any school, church, or daycare center; or alternatively, proof that any school, church, or daycare center that is located within 300 feet of a building to be used by the applicant did not occupy that location prior to the applicant initially seeking to become licensed to operate at the location and a signed attestation that the laboratory will not operate in any location within 300 feet of a school, church, or daycare center.

☐ 24. MCP License Identification Card Request (https://nmhealth.org/publication/view/form/138/ for all employees are to be submitted, employee card requests are to include the following:

- Department of Public Safety and national background checks must be submitted with application and must be current or conducted within 90 days.
- Employee valid NM ID or Driver License.
- Employee HIPAA training certifications.

INITIAL EACH BOX below to signify full compliance and comprehension of the laboratory application process, as per 7.34.4 NMAC

☐ I certify, employee applications for MCP employee cards are attached, completed in full, and a cover page is included along with valid ID or Driver License.

☐ I certify, each of the check boxes have been checked, indicative of each required item has been fulfilled and will be submitted with this application.

☐ I certify, I have read and have full access to 7.34.4 NMAC regulations.

☐ I certify, acknowledge and understand the Medical Cannabis laboratory regulations set forth in 7.34.4.17 NMAC, 7.34.4.18 NMAC, and 7.34.4.19 NMAC and agree to adhere to these rules.

☐ I certify all materials, as required by 7.34.4.17(D), will be maintained on the laboratory premises at all times and will be made readily available, when requested by MCP.

☐ I certify that the department may deny, withdraw, or suspend approval of a laboratory in accordance with this rule, upon determination by the department that the laboratory has violated a provision of this rule, upon failure of a proficiency test, upon the refusal of the laboratory to provide requested access to premises or materials, or upon the failure of a laboratory to comply with any standard, procedure, or protocol developed, submitted, or maintained pursuant to this rule [7.34.4.17 NMAC - Rp. 7.34.4.15 NMAC, 6/23/2020].

Please attach MCP Employee Identification card request, Department of Public Safety background and national background checks, HIPPA training certificate, copy of driver's license or identification card, and food safety handler certification if applicable. List all employees that will be working for perspective laboratory on the check list below.

FIRST, LAST NAME	PHOTO ID (Y/N)	STATE BACKGROUND CHECK (Y/N)	NATIONAL BACKGROUND CHECK (Y/N)	HIPAA CERTIFICATION (Y/N)	FOOD HANDLER SAFETY CERTIFICATE (Y/N)	JOB TITLE	LOCATION

Signing below, signifies all material in this MCP Laboratory application are acknowledged, understood and will be adhered to. All above required documentation will be submitted, simultaneously, with this application. I certify this application is correct and complete to the best of my knowledge.

Performed by:
Laboratory Representative Signature: _____ Date: _____

Secondary Review:
Laboratory Representative Signature: _____ Date: _____

THE SECTION BELOW IS FOR MCP REVIEW ONLY

Approval Year: _____

Reviewed by:
MCP
Representative
Signature: _____ Date: _____

Secondary Review:
MCP
Representative
Signature: _____ Date: _____

Application: ☐ **Approved** ☐ **Denied**
reason for denial:

_____

_____

_____

_____

_____

_____

Laboratory approval given by: _____ on

_____.

Laboratory approval expiration date:

_____.