



BLUE PAPER

A Guide to Preparing Cannabis Laboratory Business License Applications

Contents

Executive Summary	4
Application Timelines	5
Fees and Costs	6
Application Fees	6
Application Overview	7
Application Sections/Information	10
Business Ownership Disclosure	10
Facility and Operations Plan	11
Facility Plan	11
Operations Plan	13
Quality Management System	13
Security	14
Safety	15
Additional Application Items	15
Application Submission & Review	16
Hemp	17
Conclusion	17

Executive Summary

In the United States, obtaining a cannabis business license is a requirement to open a cannabis safety testing laboratory in most states that legalized medical and/or recreational marijuana consumption. The licensing process begins by preparing an application. Submitting a comprehensive application is time-consuming and benefits from the input of an experienced and multidisciplinary team. The team should include people with areas of knowledge in finance, architecture, construction, security, laboratory operations, laboratory compliance, and laboratory safety. Building a strong team and

gathering the information and documentation is a costly, time-consuming, and challenging task. However, the team will help to assemble a large amount of supporting documentation including legal and financial disclosures and prospective facility and operations plans. Having a comprehensive understanding of the timing and content of an application will help an investor understand the time and financial commitment before the decision to apply for a cannabis laboratory business license is made.



Application Timelines

Because there is no uniform federal oversight, application preparation requirements and review times vary at the state and local government levels. This point cannot be stressed enough, and it is essential to understand that until federal oversight occurs, differences in application requirements should be expected between the independent state and local governing organizations. Accordingly, this chapter will focus on the generally accepted common elements of the application process and try to highlight major differences when appropriate.

Preparing to submit a cannabis safety testing application can be a lengthy process and applicants should generally plan on a minimum of 2-6 months to prepare, submit, and receive feedback for both the state and township/city applications. This time range can easily be extended if the team has competing priorities or distractions. Some of the key determinants of time include: 1) the ability of applicants to stay organized and focused, 2) the specific state application requirements, 3) the ability of applicants to produce documentation of their business, financial, and litigation history, 4) whether applicants have prior analytical laboratory experience and/or access to existing policies and SOP's.

Working with people who have successfully completed cannabis laboratory applications before substantially increases the likelihood of meeting the anticipated timelines. Investors and business owners may choose to complete applications without previous experience, but it is more common for applicants to hire knowledgeable consultants. Consultants often include attorneys, certified public accountants, cannabis business license application specialists, and laboratory experts. Consultants will be familiar with the regulations, understand the nuances of application requirements, provide an organized and prioritized checklist for document procurement and preparation, and know which sections are going to be reviewed with more scrutiny. The benefit of using a consultant is shortening the submission timeline and reducing the possibility of the state or local government review committee requesting follow-up documentation.

Many state and local governments limit the number of business licenses that are available making the submission process competitive. In some locations, licenses are awarded in the order, a fully completed application is received, and the site inspection is passed. In other locations, a point system is used to score and rank applications, which ultimately determine whether an applicant qualifies for a license. In competitive license locations, the speed at which an application can be completed must be a high priority. In these cases, it is common for applicants to hire a consulting team, rather than an individual, in addition to their own team to ensure rapid completion since time is critically important.

Fees and Costs

Application Fees

All cannabis business license applications have a fee due at the time of submission. The application fees can vary significantly depending on location. Fees are intended to cover the costs of the regulatory agency documentation review as well as an inspection fee for the on-site assessment plus travel and per diem expenses for the auditor or audit team. See [Table 1](#) for an overview of fees. The fee may or may not be refundable. Fees are typically only a few thousand dollars, but in some states they can be much higher. For example, in New York the non-refundable application fee and refundable registration fee are \$10,000 and \$200,000, respectively, while in Utah the application fee is \$500. In some states, it is necessary to submit separate applications for both medical and recreational marijuana. Although the content of these applications may be virtually identical, the process requires appropriate licensing agency personnel review, inspection, and administrative oversight, ostensibly supporting duplicate submission fees, but also requiring additional time and effort from the applicant. While not part of the application process, it is worth noting that most states have an annual renewal fee that, like the application fee, can vary substantially by location.

Table 1: Range of fees associated with submitting a cannabis business license application.

Fee	Approximate Cost
Application fees:	\$1,000 – \$200,000
License renewal fees:	Up to \$75,000
Inspection fees:	\$1,000 - \$10,000



Application Preparation Costs

Because the specific requirements for each state application are different, expenses required to prepare the application can vary. Some requirements can be fulfilled with little to no expense while others require third party assistance and will drive cost upwards. Some examples: certain markets don't require real estate to be secured, stamped architectural blueprints of your facility, or zoning approval; a complicated business structure will increase attorney fees much more than if you are a sole individual; some states require proof of ISO 17025 accreditation documentation which is a massive cost increase in both time and money.

Minimizing costs and maximizing future revenue is always a primary goal for investors. The time it takes to prepare and submit a cannabis business license application impacts investor cost and downstream revenue. Calculating the loss of revenue from delays that prevent a laboratory from operating may help to focus many application preparation decisions. **Assuming the average revenue per safety test is \$400 and a lab can process 50 tests per day with one set of instrumentation, then every day that an application is delayed defers $\$400 \times 50 = \$20,000$ per day of downstream revenue.** With this in mind, it is not surprising that many applicants chose to work with consultants who have previous experience organizing, preparing, and submitting the necessary documentation. Consultants who state that an application can be prepared for a comparatively low price (\$5,000) on an hourly basis should be questioned about their previous experience and successes. If an experienced laboratory consultant charges \$250/hr (far less than most attorneys) that provides for only 20 hours of work. Applications regularly exceed 100 pages and it is virtually impossible for a customized cannabis laboratory license application to be prepared in 20 hours.

Application Overview

States and local governments have the authority to create their own cannabis business license application requirements. Variations between them are common, but two general categories of information are expected: 1) business and personal disclosures, including legal and financial disclosures, business background checks, and demonstration of financial security to qualify applicants for the right to submit a complete business application, and 2) laboratory information, including a physical description of the facility and a comprehensive operations plan. In addition to state licensing, local government licensing is normally required. Fortunately, this application information tends to closely mirror the state application. The business and personal disclosure phase is relatively straightforward as it relies on gathering preexisting information. However, individuals with the ability to invest in a cannabis laboratory often have a substantial number of disclosures that take time to acquire. The laboratory information phase is like a comprehensive business plan without detailed financial statements and requires the applicant to provide a large amount of original descriptive detail.

States and townships work hard to provide support and guidance to applicants, but because the cannabis industry is still in its infancy, changes to application documents and application requirements are common. Something as simple as a missing form or using an outdated form can stall an application review. Therefore, it is imperative to use the most current application forms and understand the state licensing structure. See [Table 2](#) for website links to currently available state application forms.

Applicants should download the most current information from the state and township and understand all application requirements. This packet of information generally includes 5 sets of documents: 1) state government application forms, 2) local government application forms, 3) any application guidance documents and/or technical bulletins, 4) a copy of the state legislation approving marijuana testing facilities, and 5) a copy of the local government ordinances approving medical and/or recreational marijuana. Although regulatory agencies

often provide summary checklists, it is highly recommended that these are converted into a single consolidated spreadsheet that lists action item, priority, responsible person/party, due date, and comments so task progress can be tracked carefully. Because of the volume of information, without a robust organization system it is easy to overlook required application elements and experience unnecessary and frustrating delays.

Laboratory licenses have typically not been as competitive as cultivation and dispensary licenses so the need for differentiation is decreased. However, many of the principles other license types use to elevate themselves from the competition can still be incorporated into the application. While there is a shift in public perception toward increased acceptance of marijuana, investors who to enter the industry or want to apply for a new license should consider making community impact and perception a priority. Being able to describe any additional value to the state and local communities is a tremendous differentiator. This may include sections explaining how the laboratory will engage with the local community, provide community benefit, and offer educational support. Laboratories have an advantage over retailers and growers, since in addition to creating high paying jobs, they can also claim that they are providing the community a safety benefit by ensuring that cannabis products are free of harmful contaminants. Developing an educational community outreach program to share information about the potential safety concerns of consuming cannabis and how laboratory services reduce those risks is a highly recommended activity. Think about working with local not-for-profit groups and establishing relationships with local and state officials by attending meetings.

Some states offer a research use license application that allows the holder to engage in research and development testing. Where available and allowable, this can be used as an opportunity for safety compliance facilities to begin method validation on cannabis and cannabis products without having to meet the infrastructure requirements of a regulated compliance testing laboratory.

Table 2: URL's for State Cannabis Laboratory Business License Application Forms.

Alabama	No application at this time
Alaska	https://www.commerce.alaska.gov/web/amco/MarijuanaLicenseApplication.aspx
Arizona	https://www.azdhs.gov/licensing/medical-marijuana/index.php#labs
Arkansas	https://www.healthy.arkansas.gov/images/uploads/pdf/Lab_Form_20170706.pdf
California	https://bcc.ca.gov/clear/forms.html
Colorado	https://www.colorado.gov/pacific/enforcement/med-new-regulated-marijuana-business-license-application
Connecticut	https://portal.ct.gov/DCP/Medical-Marijuana-Program/Medical-Marijuana-Program
Delaware	https://dhss.delaware.gov/dhss/dph/hsp/medmarhome.html
Florida	https://knowthefactsmmj.com/rules-and-regulations/
Georgia	No application at this time
Hawaii	https://health.hawaii.gov/statelab/wp-content/blogs.dir/10/files/2013/07/2016_Medical_Marijuana_Testing_Facility_Application.pdf
Idaho	No application at this time
Illinois	https://www2.illinois.gov/sites/mcpp/Documents/Lab-Application-Approval-Form.pdf
Indiana	https://www.oisc.purdue.edu/hemp/index.html
Iowa	https://idph.iowa.gov/omc/For-Manufacturers-and-Dispensaries
Kansas	No application at this time

Continued on the next page.

Kentucky	No application at this time
Louisiana	No application at this time
Maine	https://www.maine.gov/dafs/omp/adult-use/applications-forms
Maryland	https://mmcc.maryland.gov/Pages/testinglabs.aspx
Massachusetts	https://www.mass.gov/how-to/apply-for-an-independent-testing-laboratory-certificate-of-registration
Michigan	https://www.michigan.gov/lara/0,4601,7-154-89334_79571_87302---,00.html
Minnesota	https://www.health.state.mn.us/people/cannabis/manufacture/lab/index.html
Mississippi	No application at this time
Missouri	https://health.mo.gov/safety/medical-marijuana/how-to-apply-fi.php
Montana	https://dphhs.mt.gov/marijuana/laboratories
Nebraska	No application at this time
Nevada	https://tax.nv.gov/FAQs/Marijuana_License_Applications/
New Hampshire	No application at this time
New Jersey	https://www.nj.gov/health/medicalmarijuana/alt-treatment-centers/applications.shtml
New Mexico	https://nmhealth.org/about/mcp/svcs/
New York	https://www.wadsworth.org/regulatory/elap/medical-marijuana
North Carolina	No application at this time
North Dakota	https://www.health.nd.gov/mm
Ohio	https://medicalmarijuana.ohio.gov/testing
Oklahoma	http://omma.ok.gov/laboratory-application-information
Oregon	https://www.oregon.gov/olcc/marijuana/Pages/Recreational-Marijuana-Licensing.aspx#Labs
Pennsylvania	https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Laboratories.aspx
Rhode Island	https://health.ri.gov/applications/MMTestingLabPreliminary.pdf
South Carolina	No application at this time
South Dakota	No application at this time
Tennessee	No application at this time
Texas	No application at this time
Utah	https://medicalcannabis.utah.gov/production/labs/
Vermont	No application at this time
Virginia	https://www.dhp.virginia.gov/pharmacy/PharmaceuticalProcessing/default.htm
Washington	https://lcb.wa.gov/mj2015/testing-facility-criteria
West Virginia	https://dhhr.wv.gov/bph/Pages/Medical-Cannabis-Program.aspx
Wisconsin	https://datcp.wi.gov/Pages/Programs_Services/IHLicRegFee.aspx
Wyoming	No application at this time

Application Sections/Information

Business Ownership Disclosure

States and townships frequently use a "pre-qualification" application to understand who is in control of any cannabis business, the level and source of financial resources backing them, and to obtain information about their legal history. These legal and financial disclosures, business background checks, and demonstrations of financial security are used to qualify applicants for the right to submit a complete business application. [Table 3](#) provides a list of common required application ownership disclosure documents. It is recommended to consult

an attorney and/or CPA for advice for guidance about these documents and disclosures, so they align with application requirements.

It is a common requirement for any business unit applying for a marijuana license to be formed in the state in which the laboratory will be located. Frequently, members of the business have a residency requirement and must maintain residency if a license is issued.

Table 3: Common business and personal application disclosures

Business Disclosures
Business formation documents
Corporate governance documents
Operating or partnership agreements
Agreements relating to profit/loss sharing
Ownership structure including an organizational chart
Business Affidavits
Business liability insurance
Permission to lease/purchase facility space
Adequate capitalization and source
Proof of meeting labor requirements
Personal Disclosures
Criminal history record check including misdemeanors, felonies, arrests/citations
Fingerprint cards
Social security number
Full disclosure of past bankruptcies and loan defaults
Child support and alimony payments
Individual and personal tax returns
Personal affidavits/attestations
Bank statements
Tax check authorization
Investigation authorization

Facility and Operations Plan

The facility and operations plans are critical and lengthy sections of the application much like a comprehensive business plan without financial statements. Depending on the state and local government, minor differences in requirements for these sections are expected, but practically all require a core set of common information. [Table 4](#) provides an overview of documentation that should be anticipated in most facility and operations plans.

Facility Plan

Most states have enacted "Green Zone" legislation that allow local governments to opt in or opt out of permitting cannabis related businesses. Assuming an applicant has identified a green zone location that allows safety testing laboratories, specific zoning restrictions need to be considered. Zoning distance buffers are common and include being a minimum prescribed distance from any elementary school, middle school, high school, college or university, either public or private, including child care or day care facility, to ensure community compliance with Federal "Drug-Free School Zone" requirements; any church, house of worship or other religious facility or institution; any residential zoning district or existing residential dwelling; any halfway house or correctional facility; and any private park. As a result, finding properly zoned real estate can be one of the most difficult – yet important – aspects of starting a cannabis laboratory. During property identification and selection period is a good time to create boundary sketches which can be made by obtaining satellite images from Google Maps. Ensure a distance legend is included.

Even though a building may be in a green zone and meet all zoning restrictions, few buildings are well suited for a laboratory. Any building is very unlikely, in its unmodified state, to meet the infrastructure requirements of a laboratory and the applicant should expect to do more tenant improvements than a typical office environment. Including someone experienced in laboratory design and workflow can be very helpful to understand potential building infrastructure constraints before a lease is signed or a purchase is made.

Once property access has been secured, the applicant needs to demonstrate a lease or proof of building ownership. The intent to operate a cannabis safety testing laboratory should be discussed well in advance of any lease agreement as many landlords are opposed to being associated with marijuana-related activities. A letter that acknowledges and approves use of the facility for should be included whether the structure is leased or owned.

The level of detail in floor plans and the trueness to the final physical space required varies widely among states and local governments. In a few, no floor plans are required, but it is more common to expect identification of all doors (or other points of ingress or egress), walls, partitions, counters, and windows; fire walls; the location of all cameras, assigning each camera a number or other unique identifier; and a clear designation of the limited access or restricted area boundary within and outside the building. If the laboratory has multiple floors, it is necessary to submit a floor plan for each floor. While placeholder floor plans can often be submitted, a better strategy is to work with an architect with previous laboratory design experience and spend the time to design the final laboratory layout.

Table 4: Common Facility and Operations Plan Application Sections

Facility
Building zoning requirements showing distance restrictions
Evidence of legal right to occupy and use the proposed premises location
A boundary sketch and floor plans for the proposed premises
Operation
Quality management plan
Standard operating procedures
Security plan including limited access areas
Sample transport and transfer procedures
Inventory control plan
Marijuana storage plans
Marketing and advertising plan
Staffing plan
Fire safety plan
Hazardous waste management plan
Less frequently requested
Architect stamped floor plan schematics
Instrumentation/equipment
ISO/IEC accreditation

Because commercial structures are widely different, cannabis testing laboratories are always a custom build. Good laboratory design creates a safe and efficient workflow that contemplates many different needs. Some of the planning points include: minimizing staff movement; providing for common and limited access areas; separate areas for enclosed sample receipt, accessioning, sample storage, chemical and biological waste storage; security surveillance; laboratory instrument infrastructure including power (220V and 110V); industrial gas generation; HVAC systems for venting; laboratory bench arrangement; and water for sinks, safety showers, and eyewash stations.

Workflow is often overlooked in spaces that are being converted from general use into a laboratory. Ideally, a good laboratory design would have a single path workflow in which samples and people move in a manner that limits retracing steps and maximizes safety. A well thought-out floor plan will reduce distance between key working areas and keep areas where the different pre-analytical, analytical, and post-analytical steps occur separated. For example, in addition to complicating the restricted area access plan, it is not ideal for staff to have to move hazardous waste from an analytical lab area through a sample receipt area to a storage area on the other side of the building.

Operations Plan

The major categories of information in the operations plan include quality, safety, and security. Quality and safety are foundations of any analytical laboratory, i.e. research and development, clinical diagnostics, environmental testing, cannabis safety, etc. Without them, the accuracy and reliability of testing data is suspect and the potential exists to expose employees to dangerous working conditions. In addition to these two key initiatives, cannabis safety testing laboratories must also prevent sample diversion, so applications must include a thorough security section.

Quality Management System

Applicants should emphasize and value quality above all since providing accurate and reliable data – a byproduct of quality – is the core function of all laboratories. Therefore, a comprehensive quality management system (QMS) is critically important for overall laboratory operations. A QMS is a set of documents created over time that describe: how the laboratory will commit to producing quality processes and data; writing, following, and documenting standard operating procedures (SOP's); collecting, analyzing, summarizing, and sharing operational data; preparing for new accreditations, inspections, and audits; investing in staff education and training; and performing regular proficiency testing. It is highly recommended that applicants have someone with laboratory compliance and regulatory experience assist with developing the quality plan since ISO 17025 accreditation is dependent on these documents.



ISO 17025

Standard Operating Procedures (SOP's) are required as part of the QMS for any analytical laboratory. SOP's are written to describe the step-by-step process for completing a task with sufficient detail so that anyone with the appropriate training and skills should be able to reasonably complete without assistance. These documents help to provide a consistent approach to performing laboratory work, streamline laboratory activities, help reduce variation in testing results, and mitigate loss of knowledge during staff turnover. While laboratory staff tend to focus on the analytical method SOP's - those directly related to the process of testing, pre- and post-analytical activities (e.g. sampling, transport, accessioning, ordering, reporting, etc.) should not be ignored as poor performance in those areas will impact the accuracy of results. The most difficult SOP's to prepare are typically the analytical method and reporting SOP's. If these are required for an application, an early strategy is to rely on protocols provided by instrument and LIS vendors. However, it should be expected that before the laboratory can be operational, they will need to be modified to reflect actual instead of proposed activities.



Security

Security is carefully scrutinized in all cannabis business applications, not just safety testing laboratories, because controlled substances will be transported, handled, stored, and disposed of at the facility. The security plan is a detailed document which describes the physical and electronic safeguards that will be used throughout the facility. Physical barriers include exterior fencing, internal walls and doors that demarcate unrestricted and controlled zone access, key card operated magnetic door locks, doors with standard key locks, visitor sign-in logs, and the possibility of an on-site security guard. Electronic security includes the location of high-definition video cameras that can create timestamped images and capture 100% of the area in the facility where cannabis may be handled, motion detectors, glass break sensors, and an alarm system. It is good business practice to hire a licensed security firm, who are at all times responsible for on-site monitoring of all intrusion equipment, and authorizing all entrance by staff, visitors and delivery vehicles. Most facilities will need a dedicated IT room with a server that will store all continuously recorded and monitored video for a minimum of 30 days and provide real-time on- and off-site access to regulators and law enforcement.



Safety

Because of the potentially hazardous nature of analytical chemistry, microbial pathogens, industrial gases, and waste storage – both chemical and biological – license applications need to have a robust safety plan. The purpose of the safety plan is to protect the welfare of anyone who may enter the facility. For the application, a safety plan for chemicals should include a list of chemicals in the facility and the storage locations and conditions for: acids, bases, and water-reactive chemicals by class; flammables by National Fire Protection Agency (NFPA) standards; peroxides; and oxidizers. The safety plan for industrial gases and volatile chemicals should address local exhaust ventilation (air exchanges per hour) to ensure that dangerous gases do not accumulate in the facility, as well as a plan for gas detection and automatic shutoff. The safety plan for biohazardous materials should include descriptions of biosafety hoods, biological waste containment, and personal protective equipment. Standard laboratory safety items such as locations of showers, eyewash stations, chemical spill clean-up kits, should be discussed and cross-referenced to the floor plan.

Laboratory operations generate hazardous waste that requires proper storage and disposal. This waste should be stored in an independent space, separate from other consumables and workflow. The application should include a description of how hazardous waste will be properly contained, sealed,

picked up, and disposed of by a licensed hazardous waste transporter for treatment in compliance with all federal, state, and local regulations. Air quality is becoming increasingly important in applications, since the testing of marijuana is a source of both odors and volatile organic compounds (VOCs) which can impact air quality and cause off-site nuisance. When needed, air quality requirements include, but are not limited to, air permits, and registration program and fees. Burning marijuana and the waste associated with the plant is not allowed, so include a description for how residual sample not used in the testing process will be disposed of in a safe and proper manner.

Additional Application Items

Although quality, safety, and security are the primary focus of the application, additional smaller elements may be required ([Table 4](#)). A local government notice affidavit is often required for marijuana establishment license applications when a proposed premise is located within a local government. As soon as practical after initiating a marijuana license application, an applicant should provide notice of the application to the public by submitting a copy of the application to each local government and any community council in the area of the proposed licensed premises. The local government usually has a reasonable window (30 days is common) to respond with an approval, objection, or no response to your license application.

In some states, providing evidence of additional community support is a desirable addition. These may include being a certified woman- or minority-owned business, describing plans for environmentally friendly operations, facilitating medical cannabis research, plans to positively impact your local community, plans to combat substance abuse, and employee-friendly policies.

Tracking of marijuana from seed to sale to prevent diversion and to facilitate product recalls is a standard state requirement. Two marijuana traceability software systems are the industry standards: Metrc and BioTrackTHC. Before a full license is granted, marijuana testing laboratory employees need to train on how to use the software and provide documentation of successful completion.

Application Submission & Review

Once the application packet is complete, it must be submitted to the state and local government. Submission may be paper or electronic, but it is highly recommended to use an online submission portal instead of paper whenever possible since everything is timestamped and it is much harder for electronic copies to get lost. It is common for the state to require a review and acknowledgment from the local government before it will be accepted creating a staggered submission process.

After the necessary documents are provided to the appropriate governing bodies, a marijuana facility license investigator is assigned and contacts the applicant to verify information and help answer questions pertaining to the application process. The license investigator may communicate any additional requirements for the application including revisions or additional information related to documents that were submitted, additional documents related to persons or entities with a financial interest in the business, additional information related to the criminal history of certain persons with a financial interest in the business, and additional information related to the facility and/or the operations plan. Failure to provide any requested information may result in denial or revocation of a license.

The laboratory licensing process is long and complex and designed to eliminate unqualified applicants. Common issues include: missing information; failure to meet basic licensing requirements; objection from the local authority; premise is located within 1000 ft of a restricted entity; questionable source and/or amount of funding; indicators of hidden ownership; criminal history, i.e. conviction of certain felonies, conviction of a gross or simple misdemeanor involving liquor or drugs, any series of violations that show a disregard for the law; and misrepresentation of fact.

Once the application review is finished and deemed complete, the marijuana facility licensing investigator will arrange a time to visit the laboratory to perform a visual inspection by confirming the items described in the application. Frequently, the investigator will bring a small team with specific expertise to help distribute the workload. The

team will review a long list of items including, at a minimum: a physical inspection of the premises to evaluate the orderliness of the physical layout; review of environmental monitoring for industrial gas safety; implementation of controlled access areas for storage of marijuana test samples, waste, and reference standards; sufficient space allocation for each testing area; a review of personnel records for the laboratory director, testing personnel, and ancillary staff; a review of quality assurance protocols; procedures for the transport and disposal of unused marijuana, marijuana products and waste; the use of a record system that allows for readily retrievable test results; verifying that complete testing SOP's, with current approval by the laboratory director, are readily available to staff; and a chain of custody documentation from receipt to disposal.

Because of the complexity of both the application and laboratory operations, it is not uncommon for minor delinquencies to be discovered. Laboratories are allowed sufficient time to correct any problems. Assuming delinquencies are resolved, a short follow-up inspection may occur after which the laboratory will be granted a temporary or full license, depending on whether ISO 17025 accreditation is part of the application.

Some states use a single step application process allowing the laboratory to show they are in the process of working on ISO 17025 accreditation, or, if the state sets a deadline for accreditation (usually 1 year from granting of the temporary license), then the laboratory will quickly shift its focus to method validation activities. However, many states use a two-step licensing process. In the first step, a laboratory that has passed a security and safety inspection may be granted a provisional or temporary license that allows them to obtain and handle cannabis samples. This allows a laboratory to develop technical methods and corresponding SOP's that reflect actual activities rather than what they propose will work. The second step, done in collaboration with the state, is to have the state prospectively review and sign off method validation protocols and summary data so that the laboratory has some affirmation that their work will meet the state inspection requirements.

Hemp

In October 2019 the USDA published the interim final rule, "Establishment of a Domestic Hemp Production Program". This document laid a strong foundation for a national hemp policy by allowing for interstate transfer, removing any uncertainty about the requirement to test for the **total potential** delta-9 tetrahydrocannabinol concentration, and requiring that laboratories register with the U.S. Drug Enforcement Agency (DEA). While a licensed marijuana testing facility can provide all the necessary testing required for hemp, it may not bypass the step of registering with DEA.

Interestingly, soon after the legislation was passed, the requirement was [temporarily delayed](#). This was because of the overwhelming number of industry stakeholders and consumers who expressed a concern about the limited number of DEA certified hemp testing laboratories and how that would impact the supply of cannabidiol (CBD). Under this guidance, the testing can be conducted by labs that are not yet registered with DEA until the final rule is published, or Oct. 31, 2021, whichever comes

first. This is intended to allow more time to increase DEA-registered analytical lab capacity. It is strongly recommended that laboratories who intend to offer hemp testing services do not wait to begin the [registration process](#). The registration application is 2 pages long and requests general information. It is not nearly as complicated as a state cannabis business license application but – importantly – it requires the state laboratory license number. Obtaining a state laboratory license number requires a separate state application unrelated to marijuana testing. The intent of requiring the state license is to show that the laboratory is authorized to prescribe, distribute, dispense, conduct research, or otherwise handle the controlled substances in the schedules for which are being applied under the laws of the state or jurisdiction in which it is operating or proposes to operate. The legal landscape for hemp and marijuana are very different and anyone wishing to test both cannabis plants within the same facility should consult an attorney early in the planning process for guidance.

Conclusion

Cannabis testing laboratory business applications are long, complex, and require a large amount of highly detailed information. It is highly recommended to work with an experienced team who has previous experience completing successful applications since they will understand required disclosures and be able to successfully navigate the facility and operations plan requirements.

About E4 Bioscience

E4 Bioscience helps cannabis investors and laboratory teams design, build, equip, operate, market and maintain compliant cannabis laboratories. Whether a building a new lab or retrofitting an active lab, our team offers value based solutions to avoid delays, generate sustainable revenue, and maintain compliance.

[Please contact us if you would like to schedule a 1-hour free discovery call or Webex.](#)

If you found this helpful, have recommendations about how we can improve, or want to provide suggestions for topics you would like to read about in our next blue paper, we'd love to hear from you! If you found an error, outdated information, or would like to sponsor a blue paper, we'd like to know that, too.



Shaun R. Opie, PhD CEO and Managing Partner

Dr. Opie is a cannabis ninja, science geek, and serial entrepreneur. He has co-founded and operated several laboratories in different verticals including research and development, clinical diagnostics, and cannabis safety testing. His ventures have all been privately held and performed regulated, high-complexity testing. His contribution to laboratory operations include business planning, laboratory design and construction, obtaining multiple accreditations and licenses, compliance, technology assessment and selection, assay design & validation, reimbursement strategy, staffing, and extensive content marketing.

Dr. Opie is committed to educating others and has held several adjunct faculty appointments at nationally recognized universities. He spent 2 years as an [Entrepreneurship Expert](#) at the [W.P. Carey School of Business](#) at [Arizona State University](#) to advise student and faculty entrepreneurs about business planning, financial modeling, pre-revenue venture funding, venture development and growth strategies. He is currently a participating member of the [AOAC International - Cannabis Analytical Science Program](#), and a lecturer on cannabis laboratory compliance. He is an invited editor for a textbook being printed and distributed by the global publisher [Springer Nature](#) in Q4 2020 titled, "Cannabis Laboratory Planning, Design, and Operations".





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