

# Medical Marijuana Facility Inspection Readiness Guide



## Introduction and Medical Marijuana Facility Inspection Readiness

The Facility License & Compliance Section (FL&CS) has developed the following Medical Marijuana Facility Inspection Readiness Guide to provide guidance and links to helpful information about the Commencement Inspection process. As new guidance is developed or needed, the FL&CS will update the guide to help support Missouri Medical Marijuana licensed or certified facilities. Facilities that follow the guidance in this document, along with other information provided by the Department, will be better prepared to pass the Commencement Inspection and begin to operate in Missouri. This guidance document provides information to supplement DHSS rules and regulations for licensed facilities. Please visit <https://health.mo.gov/safety/medical-marijuana/index.php> for a copy of the rules. This guide is not intended to be an all-inclusive list of requirements for Commencement Inspection. Each facility is responsible to ensure all requirements of 19 CSR 30-95 have been met. Each facility should work in coordination with their assigned Compliance Officer to clarify any questions or concerns regarding their Commencement Inspection.

## Applicable Rules and Definitions

Licensed and certified medical marijuana facilities are advised to review and understand the rules related to the State’s Medical Marijuana Program, which include Code of State Regulations (CSR) Division 30, [Chapter 95](#):

Definitions	Chapter 95.010
General Provisions	Chapter 95.020
Generally Applicable Provisions	Chapter 95.025
Additional Licensing Procedures	Chapter 95.028
Qualifying Patient/Primary Caregiver	Chapter 95.030
Medical Marijuana Facilities Generally	Chapter 95.040
Cultivation	Chapter 95.050
Infused Products Manufacturing Facility	Chapter 95.060
Testing Facility	Chapter 95.070
Dispensary Facility	Chapter 95.080
Seed-to-Sale Tracking	Chapter 95.090
Transportation Facility	Chapter 95.100
Physicians	Chapter 95.110

## Approval to Operate

The issuance of a facility license or certification does not authorize the facility to begin cultivating, manufacturing, dispensing, testing, or transporting medical marijuana. A facility will be granted written final approval to operate upon passing a Commencement Inspection from the Section for Medical Marijuana Regulation (19 CSR 30-95.040).

Pursuant to 19 CSR 30-95.040(5), once a licensed or certified facility believes it will, within a month, be ready to begin operations and meet all state and local requirements for its facility, it shall request that the Department conduct a Commencement Inspection to confirm the facility is in compliance with the requirements of this Chapter.

As a reminder, licensees have one (1) year from the date of the license or certification to pass a Commencement Inspection and receive final approval to operate. Pursuant to 19 CSR 30-95.040 (1)(F)4, if a facility is granted a license or certification but has not passed a Commencement Inspection within one (1) year of the department issuing the license or certification, the license or certification may be revoked.

## PREREQUISITES FOR INSPECTION SCHEDULING

The Department asks that licensees contact the FL&CS to request an inspection when within a month the facility will be ready to begin operations and meet all state and local requirements. The facility must also have completed the minimum standards verification process, attended the mandatory Facility Welcome Meeting, and have no outstanding Business Change Request that will impact the facility's Commencement Inspection.

Department staff are working diligently to ensure that all licensees are inspected in a timely manner that corresponds as closely as possible with individual project timelines. Conducting multiple inspections of facilities that are not in compliance as a result of incomplete execution of plans or execution of plans in conflict with responses to facility application Evaluation Criteria Scoring questions, may cause delays in the overall timeline for completing the Commencement Inspection.

### Mandatory Meeting

A representative for each licensed facility must have attended the Department's mandatory Facility Welcome Meeting on March 4<sup>th</sup> or 5<sup>th</sup>, 2020. If you are a new licensed or certified facility that was not licensed at that time, please contact the Compliance Unit at [mmlicenses@health.mo.gov](mailto:mmlicenses@health.mo.gov) for guidance.

### Determination of Compliance with Materials Submitted with your Application

The materials submitted with your application will serve as your guide in preparing for this part of the inspection. Please be prepared to address questions from DHSS staff regarding any information presented with your application, including the subsections of each plan submitted. Department staff will review application documentation prior to the on-site inspection and will examine the facility itself to determine alignment with the information presented in your application. This includes, but is not limited to the following:

- Standard Operating Procedures (SOPs)
- Organizational chart
- Facility layout
- Employee training materials
- Transportation policies/procedures

Any facility/structural change requests or variances submitted to the Department during the period that were approved in writing by Department staff will supersede the specifications from the original application.

All licensed or certified cultivation, dispensary, manufacturing, testing, and transportation facilities must seek and obtain the Department’s approval before they may –

- Assign, sell, give, lease, sublicense, or otherwise transfer its license to any other entity
- Make ownership changes great than 10%
- Materially deviate from the proposed physical design, including location
- Combine licensed facilities at a single location
- Construct offsite warehouses

## Seed-to-Sale Vendors

If the licensed or certified facility chooses to use a seed-to-sale system for inventory tracking, point-of-sale services, etc., please ensure that the vendor being used has been certified by the Section for Medical Marijuana Regulation and has received an API key from Missouri’s Track and Trace system, Metrc. To check vendors that have been approved to be used by Missouri facilities, go to <https://www.metrc.com/missouri>.

## Metrc Credentialing

Metrc is Missouri’s Track and Trace system. Every Missouri medical marijuana licensed or certified facility must use Metrc. Once a facility has requested a Commencement Inspection, a facility owner or approved designee may request to be credentialed into Metrc as an administrator and is required to sign-up for the new business training course. More information and Metrc Next Steps can be found at <https://www.metrc.com/missouri>.

## State Track and Trace: Metrc Training

Prior to the physical Commencement Inspection, at a minimum, the statewide track and trace system must be established at your facility, and your facility administrator must be able to log in during the inspection to demonstrate that the system is accessible and ready for use. *Please contact Metrc support at [support@metrc.com](mailto:support@metrc.com) or 877-566-6506 with any Metrc question or assistance on training signup and/or credentialing.*

## Agent Identification Card

All individuals that are required to have an Agent Identification (ID) card per rule, including contractors, should begin applying for their cards once the facility has requested a Commencement Inspection.

Each owner, officer, manager, contractor, employee, and other support staff of a licensed or certified cultivation, dispensary, manufacturing, testing, or transportation facility shall obtain an Agent ID card.

A contractor is a person or company that undertakes a contract with a licensed or certified facility to perform work that would include access to medical marijuana or related equipment or supplies for a time period greater than fourteen (14) days and must receive an Agent ID card. If the contractor will be on premises for fourteen days or less, they will be required to register as a guest and escorted at all times.

An owner is a person who holds any portion of the economic or voting interests of a facility and who will have access to medical marijuana or a medical marijuana facility. If an owner will not have access to medical marijuana or the medical marijuana facility they will not be required to apply and receive an Agent ID. However, if the owner visits the facility they must register as a guest and be escorted at all times while on the premises.

For all other such individuals, applications for Agent ID cards will be accepted only after an individual receives an offer of employment from a licensed or certified facility, and for those individuals, Agent ID cards must be granted before they may begin employment with a licensed or certified entity.

Agent ID card holders must have their cards accessible to them at all times while performing work in or on behalf of a facility.

## Compliance with Applicable State, Tribal, Local, and Municipal Laws and Regulations

FL&CS staff will review documentation of compliance with applicable state and local codes and ordinances, building codes, etc. in advance of the on-site inspection. Facilities will be requested to submit documentation that supports compliance for review as part of the Commencement Inspection process and prior to an on-site inspection. It is imperative that each facility is aware of their state and local requirements to obtain the appropriate documentation in advance of requesting an inspection. Documents and permit may include, but are not limited to:

- Zoning permits
- Building permits and code inspections
- Certificate of Occupancy
- Fire safety inspection
- Business license

- Water testing results within one year/ private water system local results if public, State Public Health Lab, if private
- Wastewater permits
- Solid waste permits
- Hazardous waste permit, if required
- Food Safety Inspection
- Certified Odor Control Plan
- National Type Evaluation Program Approved Scale
- Any other permits or licenses required by local or Missouri jurisdiction

Note: The Department of Natural Resources (MoDNR) provides a service to new and existing regulated facilities to assist in achieving environmental compliance. MoDNR will come to your site to meet with facility staff to explain regulatory requirements, help a regulated entity achieve and maintain compliance with permitting requirements, answer questions regarding permits and discuss issues that arise. Please note, these are not comprehensive inspections, but rather a guide to compliance. The Compliance Unit strongly encourages each facility to take advantage of this resource in advance of a Commencement Inspection to ensure all required permits have been received. Facilities may contact their MoDNR regional office to request a compliance assistance. For more information visit at: <https://dnr.mo.gov/regions/>.

## Records and Logs

Several records and logs are required to be maintained at the facility under the recordkeeping provisions of the Medical Marijuana Program. During the inspection process, Department staff will review the logs to ensure that all of the required information will be tracked once your facility is operational and the logs are put into use. (For future compliance inspections, logs will be checked to ensure they are being utilized properly.) For the Commencement Inspection, licensees need only demonstrate that the logs have been created, are formatted to record the required information and there are instructions for use by the facility.

Please be aware of the timeframes records must be kept. For example, facilities must keep records of the final disposal destinations of all wastes and trip logs for at least five (5) years. For any records that will be kept electronically, be prepared to demonstrate that any such electronic record keeping system complies with the requirements.

## Scale

All weighing and measuring of medical marijuana required by this rule must be conducted with a National Type Evaluation Program approved scale, which shall be capable of weighing and measuring accurately at all times and recalibrated at least yearly. Under Missouri law, scales must be certified by the Missouri Department of Agriculture, Division of Weights and Measures. For more information visit <https://agriculture.mo.gov/weights/device/scales.php>

## Procedures

A complete set of SOPs or operating documents demonstrating compliance with the requirements and restrictions of 19 CSR 30-95 must be available for review by Department staff during the inspection process. Documents must conform to, at a minimum, any list or structure presented with the original application. Documents must address all current and future operational tasks and should include an established method to execute future document revisions. Examples of document topic areas include, but are not limited to the following:

- Waste management
- Employee health and sanitation
- Environmental factors
- Monitoring environmental conditions
- Cleaning and sanitizing rooms and equipment
- Maintaining any equipment used to control sanitary conditions
- Equipment operations and control
- Air supply
- Inventory control
- Security
- Recall/Destruction
- Odor control
- Emergency
- Health Insurance Portability and Accountability Act

## Packaging and Labeling

To demonstrate compliance with applicable rules, sample packaging is requested to be available for any product that has been developed. Noncompliant packaging will be noted as deficient.

## Determination of Compliance with Evaluation Criteria Question Worksheets and Supporting Documentation submitted during Application

Worksheets and responses to the Evaluation Criteria Questions submitted with each facility application will serve as your guide in preparing for this part of the Commencement Inspection. Please be prepared to address questions from the Compliance Unit regarding any information presented in the application. Staff will review available documentation and examine the facility itself to determine if the facility and operation align with the information presented in the application.

In the event that the facility has deviated from their original application, the facility must note the deviation in the Inspection Form and provide an explanation of the change.

All licensed or certified cultivation, dispensary, manufacturing, testing, and transportation facilities must seek and obtain the department's approval before they may –

- Assign, sell, give, lease, sublicense, or otherwise transfer its license to any other entity
- Make ownership changes greater than 10%
- Materially deviate from the proposed physical design, including location
- Combine licensed facilities at a single location
- Construct offsite warehouses

Any departmental approved facility change by the date of Commencement Inspection will be used for the evaluation.

### Inspection of a Facility and Access

Submission of an application for a facility license or certification constitutes consent to inspection by the Department. Some inspection will be scheduled in advance, such as a Commencement Inspection. However, a Department Compliance Officer conducting an inspection is not required to provide prior notice of the inspection and, during the inspection, must be given access to all areas and property of the facility.

### Books, Records and Operations

The Department may also, at any time it determines an inspection is needed, conduct an inspection, including an inspection of any part of the premises, qualifications of personnel, methods of operation, records, and policies and procedures of a licensed or certified facility.

### Interviews

The Department may also request to interview an owner, officer, manager, contractor, employee, or other support staff of a licensed or certified facility, and the facility shall arrange for the interview to occur as soon as possible but not later than five (5) days after the Department makes the request.

### Commencement Inspection

Once a licensed or certified facility believes it will, within a month, be ready to begin operations and meet all state and local requirements for its facility, it shall request that the Department conduct a Commencement Inspection to confirm the facility is in compliance with all requirements of this chapter.

### Annual Inspection

The Department will enter and inspect at least annually, with or without notice, to ensure compliance with Article XIV and 19 CSR 30-95.



## Complaints

Upon receipt of a complaint against a facility, the Department will determine if an inspection is warranted to investigate the allegations in the complaint. In the event that an inspection is warranted, the Department, at the time of inspection, will provide the facility with a copy of the complaint and an opportunity to respond.

## Initial Notice of Violation

If the Department determines, during an inspection or otherwise, that a facility is not in compliance with the Department's regulations, the Department will issue an Initial Notice of Violation to the facility that explains how the facility has violated the Department's regulations and what remedial actions the Department expects the facility to take to correct the violation(s).

## Follow-Up Inspection

Once a facility has been notified of violation(s), the facility shall correct the violations within fifteen (15) days, and the Department will conduct a follow-up inspection within fifteen (15) to thirty (30) days to confirm the facility has corrected the violation(s). The facility shall notify the Department if it believes it needs additional time to correct the violation(s), which the Department may grant for good cause.

## Final Notice of Violation

If the Department's follow-up inspection reveals the violation(s) have not been corrected, the Department will issue a Final Notice of Violation to the facility explaining how the facility continues to violate the Department's regulations, what remedial actions the Department expects the facility to take, and notifying the facility that its license or certifications will be suspended if the specified remedial action is not taken and the violation(s) corrected within thirty (30) days.

## Suspension/Corrective Action Plan

If the violation(s) have not been corrected thirty (30) days after a Final Notice of Violation and no extension of this deadline has been granted by the Department, the facility's license or certification will be suspended, the facility will be required to cease operations, and the facility must sign a corrective action plan designed to bring the facility into compliance.

## Imminent Health Hazard

If, at any time, the Department determines a facility presents an immediate and serious threat to the health and safety of the public or of the facility's employees, the Department may order the facility to immediately suspend all or a part of its operations until the threat has been eliminated.