

Division of Cannabis Regulation

Licensee Workshop

June 2024

A.M. Agenda

Licensee Workshop – June 2024

| 09:00 | Registrant Check-in |
|-------|---|
| 09:30 | Welcome and Opening Remarks |
| 09:45 | Bureau of Business Licensing Services |
| 10:45 | Break and Networking Opportunity |
| 11:15 | Bureau of Facility Compliance – Facility Compliance Unit |

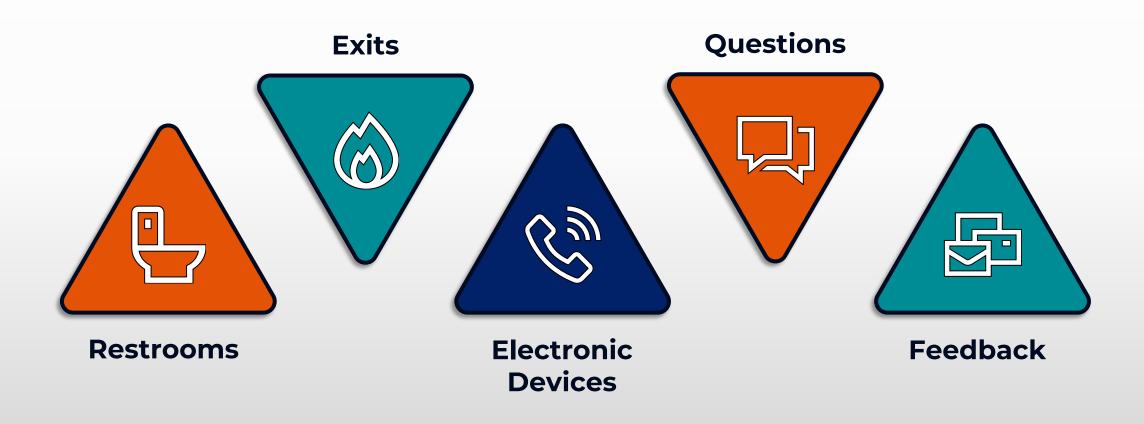
P.M. Agenda

Licensee Workshop – June 2024

| 01:45 | Bureau of Investigation and Enforcement |
|-------|---|
| 02:30 | Bureau of Facility Compliance – Compliance Assessment Unit |
| 03:15 | Break and Networking Opportunity |
| 03:45 | Bureau of Facility Compliance – Testing Research Unit |
| 04:00 | Communication, Resources and Closing Remarks |

Workshop Need to Know

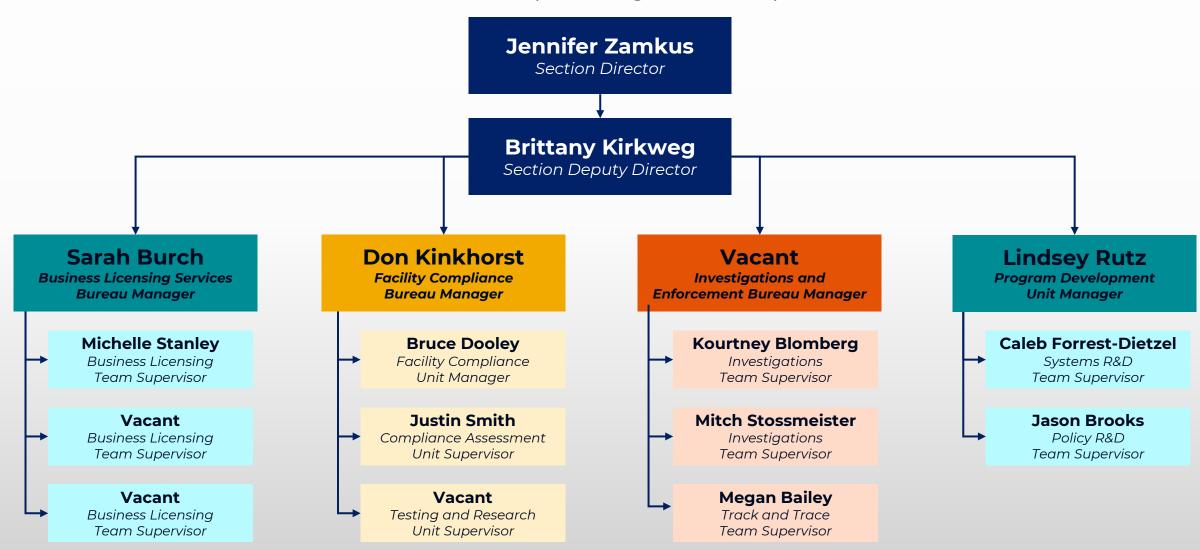
Licensee Workshop – June 2024



The Section for Compliance and Enforcement

Section for Compliance and Enforcement

Section Leadership, Managers and Supervisors



SCE Contact Information

Send any unanswered workshop questions to:

Business Licensing Services

CannabisLicense@health.mo.gov

Bureau of Facility Compliance

CannabisCompliance@health.mo.gov

Product Compliance Team

CannabisProductCompliance@health.mo.gov

Bureau of Investigation and Enforcement

CannabisComplaints@health.mo.gov

Testing and Research Unit

TestingandResearchUnit@health.mo.gov

Understanding Article XIV and 19 CSR 100-1



Article XIV

Missouri Constitution

2018

Amendment 2 Passed

On November 6, 2018, 65 percent of Missouri voters passed Amendment 2 into law, legalizing the medical use of marijuana for qualifying Missouri patients.

2022

Amendment 3 Passed

On November 8, 2022, 53 percent of Missouri voters passed Amendment 3 into law, legalizing adult use of marijuana for adults over the age of twenty-one.

General Considerations

No Variances or Waivers

Licensees and ID cardholders cannot request for a waiver or variance from Article XIV.

Foundation of 19 CSR 100-1

Article XIV provides DHSS with rule making authority. Article XIV language is echoed throughout 19 CSR 100-1.

Guidepost for Decision-Making

Article XIV is the first stop in many decision-making processes. Often, we start by asking; what does Article XIV say?



19 CSR 100-1

MO Marijuana Rules

2020

First Medical Sales

On October 16, 2018, sales to medical patients began.

2023

First Adult Use Sales

On February 3, 2023, sales to adult use consumers began.

General Considerations

Variances or Waivers

Licensees and ID cardholders may request a waiver or variance from 19 CSR 100-1; with good cause. If the rule is rooted in Article XIV, DCR cannot waive or vary from the rule requirement.

Built from Article XIV

Article XIV provides the foundation for 19 CSR 100-1. Article XIV language is echoed throughout and expanded on in 19 CSR 100-1.

Framework for Compliance

19 CSR 100-1 provides licensee's a framework for compliance. To effectively comply with rule requirements, licensees must take the chapter as whole into consideration.

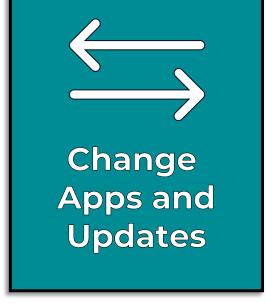


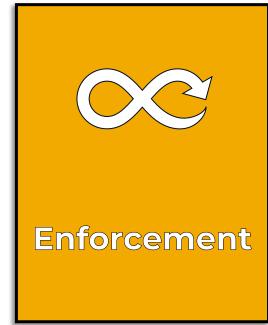
Bureau of Business Licensing Services

Licensee Workshop
June 2024

Bureau of Business Licensing Services (BLS)









Confirm compliance with application requirements

Process change applications; facilitate license updates

Monitor rule compliance, issue violations and enforce actions

Serve as resource for licensees; provide technical assistance

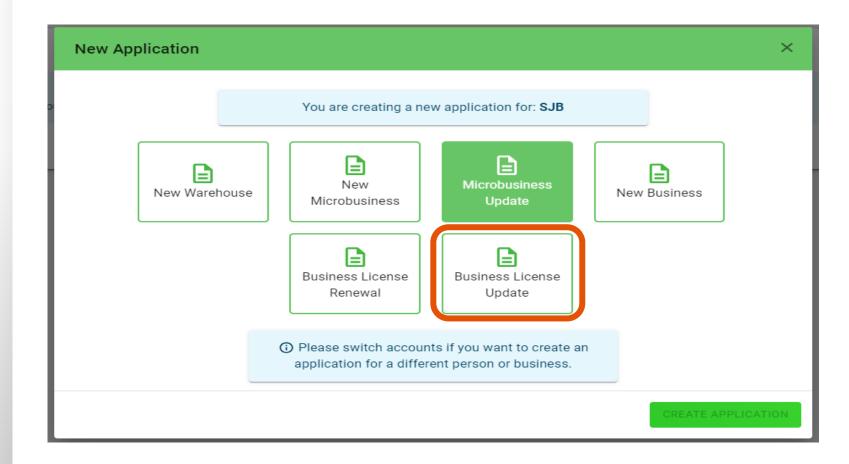
Business Change Applications 19 CSR 100-1.100(2) and 19 CSR 100-1.100(3)

- 1) Transfer to a different entity with the same ownership
- 2) Overall change in ownership of 50% or more
- 3) Change of location
- 4) Individual becoming an owner who was not previously an owner (marijuana licensees only)

Change requests

- ✓ Online registry system
- ✓ Order received
- ✓ Status update

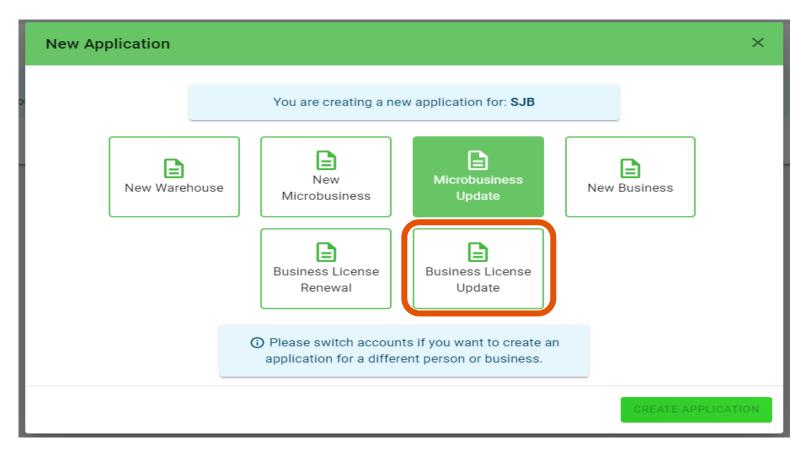
Business License Change Requests



Change requests

- 1) Processing times
- 2) Denials
- 3) Designated Contact

Business License Change Requests



DCR Website: Data and Reports Page

https://health.mo.gov/safety/cannabis/stats.php



Business Change Applications

DHSS Home » Licensing & Regulations » cannabis » business-change-app

Purpose

Marijuana and Medical facility licensees must apply for and obtain the department's approval before they may make certain changes to their ownership or facility location, as outlined in 19 CSR 100-1.100.

Application Fees

Licensees seeking to apply for a change pursuant to 19 CSR 100-1.100, must remit all required administrative and processing fees at the time of application. Licensees can remit payment at

https://magic.collectorsolutions.com/magic-ui/Login/mo-health-senior-serv &, and upload their payment receipt with their change request. The current fee schedule can be accessed at https://health.mo.gov/safety/cannabis/fees.php.

General Instructions and Considerations

Licensees should complete the appropriate Business Change Application Checklist below. All documents, including the completed checklist, should be uploaded to the **online registry portal** \mathscr{L} .

- Change the Licensee's Facility Location
- Changes that Would Result in an Individual Becoming an Owner of the Licensed Entity Who Was Not Previously an Owner
- Change of Overall Ownership Interests of Fifty Percent (50%) or More from the Last Approved Ownership of the Licensee
- Transfer a License to a Different Entity with the Same Ownership
- Full Asset Transfer of License to Different Entity (Licensee Checklist)
- Full Asset Transfer of License to Different Entity (Transferee Checklist)



https://health.mo.gov/safety/cannabis/business-change-app.php

DCR Website

Business Change Application Checklist

Licensee Name

License Number

Indicate License Type:

- Marijuana License (Includes Comprehensive, Testing, Transportation and Microbusiness)
- Medical License (Licenses designated as Medical only)

Checklist

| Verify | Department Requested Document | Licensee Uploaded Document Name(s) |
|--------|--|---------------------------------------|
| V | Proposed blueprints for the facility that detail room purpose(s), camera locations, limited access areas, access permissions, and all premises under facility control. | |
| | Documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with local distance requirements, or stating that there are none. | |
| | If the local government in which the facility will be located has enacted applicable zoning restrictions, documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with applicable zoning restrictions. | |

Checklist

Location

Blueprint

Room, purpose, cameras, limited access areas

Zoning/ Distance

Local government letter confirmation

Lease

Current signed lease <u>or</u> real estate purchase/ownership

Required

Fee Checklist Narrative

19 CSR 100-1.100(3)(A-B)

Ownership

Owner Docs

ORT
Visual
Governing

DFO

Background Check and Fingerprints Common Control

No Testing Labs or Microbusiness Required

Fees Checklist Narrative

| | | | First Name | Last Name | Entity through which the individual holds interest in the license | | | |
|------------|-----------|-------------------------|------------|-----------|---|---|-------------------------------------|----------------------------------|
| First Name | Last Name | Entity through which th | | | | urrent % of voting rest of the license** | Proposed % of financial interest*** | Proposed % of voting interest*** |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Total | | | | | | 0,000 | | |
| | | | Total | | | | | |

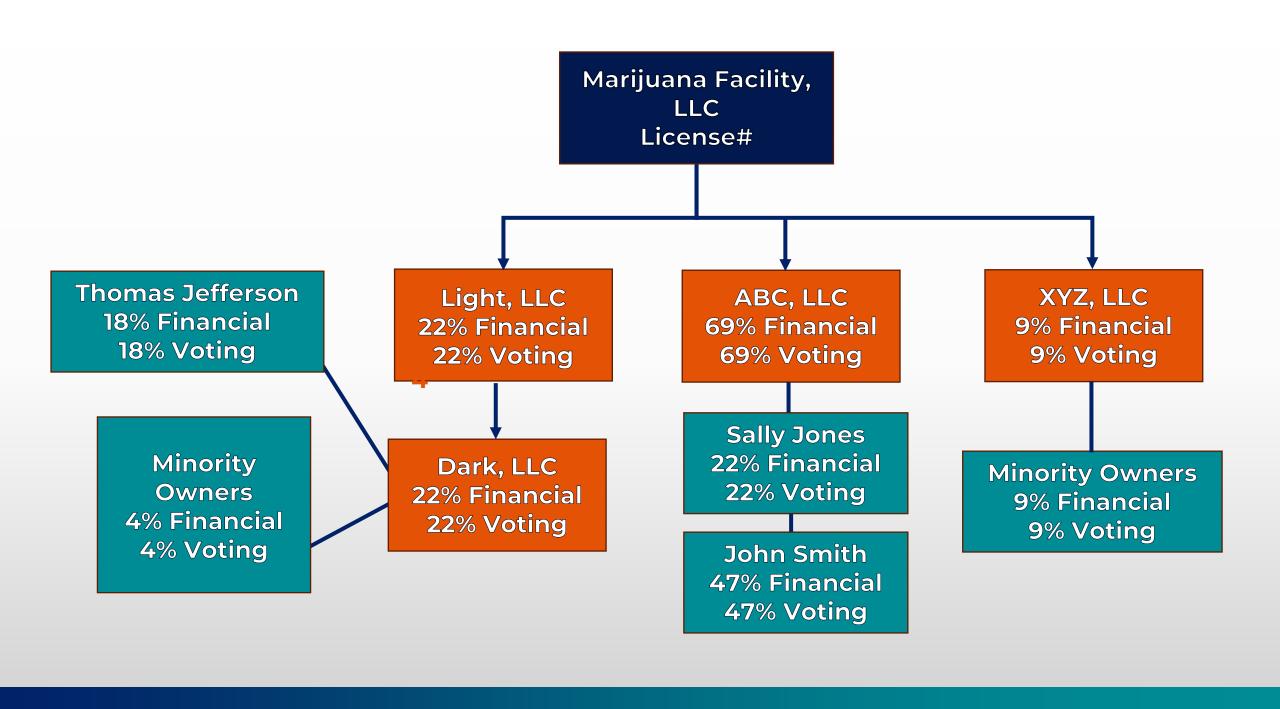
ORT

| | | Entity through which | DHSS last | DHSS last |
|------------|-----------|-------------------------|-------------|-----------|
| First Name | Last Name | the individual holds | approved | approved |
| | | interest in the license | % financial | % voting |
| Sally | Jones | ABC, LLC | 10.000 | 10.000 |
| John | Smith | ABC, LLC | 10.000 | 10.000 |
| Thomas | Jefferson | Light, LLC/Dark, LLC | 32.000 | 32.000 |
| Judy | Jetson | Light, LLC/Dark, LLC | 45.000 | 45.000 |
| Annie | Oakley | Light, LLC/Dark, LLC | 1.500 | 1.500 |
| Charlie | Chaplin | XYZ, LLC | 1.500 | 1.500 |
| | | | | |
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| | | | | |
| | | | | |
| | | | | |
| | | | | |
| Tota | | | 100.000 | 100.000 |

| First Name | Last Name | Entity through which the individual holds interest in the license | DHSS last approved % financial | DHSS last approved % voting | Current % of financial interest of the license** | Current % of voting interest of the license** |
|------------|-----------|---|--------------------------------------|-----------------------------|--|---|
| Sally | Jones | ABC, LLC | 10.000 | 10.00 | 20.0000 | 20.0000 |
| John | Smith | ABC, LLC | 10.000 | 10.00 | 14.0000 | 14.0000 |
| Thomas | Jefferson | Light, LLC/Dark, LLC | 32.000 | 32.00 | 15.0000 | 15.0000 |
| Judy | Jetson | Light, LLC/Dark, LLC | 45.000 | 45.00 | 45.0000 | 45. <mark>0000</mark> |
| Annie | Oakley | Light, LLC/Dark, LLC | 1.500 | 1.50 | 3.0000 | 3.0000 |
| Charlie | Chaplin | XYZ, LLC | 1.500 | 1.50 | 3.0000 | 3.0000 |
| | | | | | | |
| | | | | | | |
| Total | | | 100.000 | 100.00 | 100.000 | 100.000 |

| First Name | Last Name | Entity through which the individual holds interest in the license | approved | | Current % of financial interest | Current % of voting interest | Proposed % of financial interest*** | Proposed % of voting interest*** |
|------------|-----------|---|----------|---------|--|---------------------------------------|-------------------------------------|----------------------------------|
| Sally | Jones | ABC, LLC | 10.000 | 10.000 | 20.0000 | 20.0000 | 22.0000 | 22.0000 |
| John | Smith | ABC, LLC | 10.000 | 10.000 | 14.0000 | 14.0000 | 47.0000 | 47.0000 |
| Thomas | Jefferson | Light, LLC/Dark, LLC | 32.000 | 32.000 | 15.0000 | 15.0000 | 18.0000 | 18.0000 |
| Judy | Jetson | Light, LLC/Dark, LLC | 45.000 | 45.000 | 45.0000 | 45.0000 | 0.0000 | 0.0000 |
| Annie | Oakley | Light, LLC/Dark, LLC | 1.500 | 1.500 | 3.0000 | 3.0000 | 2.0000 | 2.0000 |
| Charlie | Chaplin | XYZ, LLC | 1.500 | 1.500 | 3.0000 | 3.0000 | 2.0000 | 2.0000 |
| Mark | Twain | XYZ, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 2.0000 | 2.0000 |
| King | Kong | Light, LLC/Dark, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 2.0000 | 2.0000 |
| Annie | Oakley | XYZ, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 5.0000 | 5.0000 |
| | | | | | | | | |
| | | | | | | | | |
| Tota | I | | 100.000 | 100.000 | 100.000 | 100.000 | 100.000 | 100.000 |

| First Name | Last Name | Entity through which the individual holds interest in the license | DHSS last approved % financial interest of | | Current % of financial interest | Current % of voting interest | Proposed % of financial interest*** | Proposed % of voting interest*** |
|------------|-----------|---|---|---------|--|---------------------------------------|-------------------------------------|----------------------------------|
| Sally | Jones | ABC, LLC | 10.000 | 10.000 | | | 22.0000 | 22.0000 |
| John | Smith | ABC, LLC | 10.000 | 10.000 | 14.0000 | 14.0000 | 47.0000 | 47.0000 |
| Thomas | Jefferson | Light, LLC/Dark, LLC | 32.000 | 32.000 | 15.0000 | 15.0000 | 18.0000 | 18.0000 |
| Judy | Jetson | Light, LLC/Dark, LLC | 45.000 | 45.000 | 45.0000 | 45.0000 | 0.0000 | 0.0000 |
| Annie | Oakley 2 | Light, LLC/Dark, LLC 3 | 1.500 | 1.500 | 3.0000 | 3.0000 | 2.0000 | 2.0000 |
| Charlie | Chaplin | XYZ, LLC | 1.500 | 1.500 | 3.0000 | 3.0000 | 2.0000 | 2.0000 |
| Mark | Twain | XYZ, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 2.0000 | 2.0000 |
| King | Kong 4 | Light, LLC/Dark, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 2.0000 | 2.0000 |
| Annie | Oakley | XYZ, LLC | 0.000 | 0.000 | 0.0000 | 0.0000 | 5.0000 | 5.0000 |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Total | | | 100.000 | 100.000 | 100.000 | 100.000 | 100.000 | 100.00 |



Ownership

Points to Remember

- All Names
- No Redaction
- Accumulative Since Last Approved Ownership
- New Owner
- Full Asset Transfer
 - Only after ATO
 - Must include two (2) apps

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O1 Updated Contact Info
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Changes *Must* be Made in Writing

Annual Reporting

Name Changes







CannabisLicense@health.mo.gov



573-751-6234

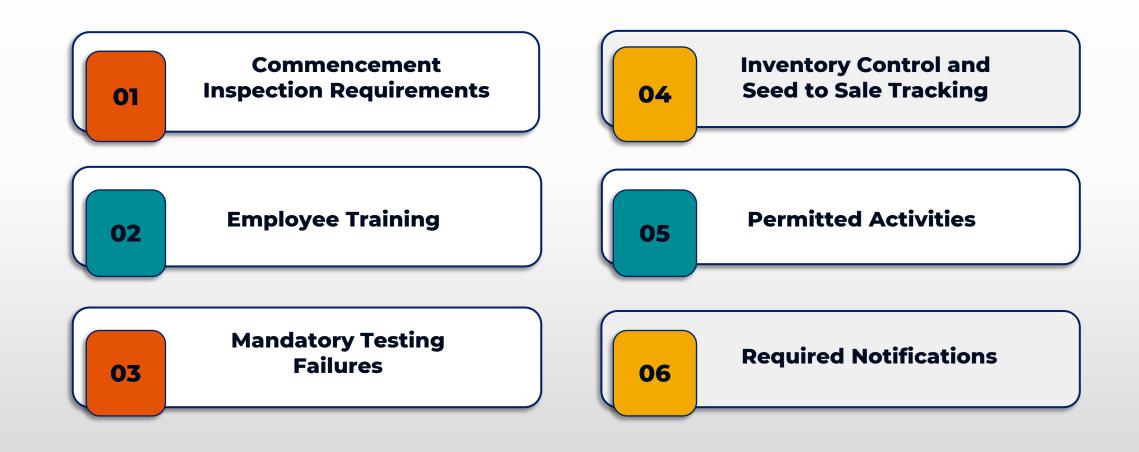


Cannabis.Mo.Gov



Facility Compliance Unit

Topics





Commencement Inspection Requests

19 CSR 100-1.030

Commencement Inspection Requests

19 CSR 100-1.030(3)(A) all licensees must request and pass a Commencement Inspection (CI) before they can:

- Begin operations under a new license/certification or new location;
 - Submit request within thirty (30) days of being ready to begin operations at the facility.
- Occupy or utilize new space for which the licensee has not previously received approval to operate, including vehicles;
- Share space with another licensee;
- Change the use of spaces

A licensee is required to submit a complete request prior to beginning construction and/or making the change, including all required documentation outlined in rule for the type of CI request.





CI Documentation Expectations

Blueprints must include:

- Entire facility including premise
- All rooms/areas clearly labeled including purpose and square footage
- Camera locations
- Limited access areas
- Access permissions

Standard Operating Procedures (SOPs): Must demonstrate that the licensee has a process in place for staff to compliantly complete a process.

- Submission of SOPs to the Department or staff acknowledgement of receipt of a licensee document does not confirm compliance with 19 CSR 100-1.
- It is the Licensee's responsibility to ensure compliance with applicable regulations.
- SOP submission:
 - SOPs relevant to CI request with the exception of new license/certification or new location (all SOPs are required)



CI Documentation Expectations (Continued)

Documentation showing compliance with applicable local, state and federal requirements:

- Licensee's responsibility to ensure compliance with applicable requirements.
- Address/name/license number must match approved license information.
- Relevant to CI request.
- For example:
 - Construction permit
 - Business license
 - Occupancy permit

CI Documentation Expectations (Continued)

Written Explanation

Must clearly explain what the licensee is requesting and must include the following at a minimum:

- **New Space** Any changes within the existing space due to the addition of new space and confirm that the licensee will comply with applicable regulations.
 - For New Space Related to a Change of Location A plan to decommission the currently approved location including transfer of marijuana product to the new location.
- **Shared Space** The operations that will occur in each shared space; any related changes to existing space; demonstrate how each licensees will retain separate processes, marijuana product inventory and inventory records, etc. as each licensee is required to function independently.
 - For Shared Vehicles Must include where the vehicle will be parked and stored overnight. Must be stored in a shared space. This includes licensees that are owned by the same entity.
- Repurposed Space The proposed changes and how the repurposed spaces will comply with applicable regulations.
- **Microbusinesses** Any changes that will occur within the existing space due to the addition of new processes and how the changes and spaces will comply with applicable regulations. Such as adding cultivation or manufacturing processes where none existed previously.

CI Documentation Expectations

(Continued)

- State-wide Track and Trace System (Metrc) Training
 - Must include:
 - Metrc training certificate
 - State-wide track and trace system training plan
 - SOPs
 - Applicable staff training log.
- Attestation
 - New Space Documentation demonstrating that the proposed new space complies with the location requirements of DCR and location and zoning requirements of the local government.
 - **Shared Space** Documentation demonstrating that the proposed sharing of space complies with local government requirements.
- Agreements Between Licensees
 - Must include each licensee's respective roles and their relationship for management, operation and maintenance of the shared spaces, including acknowledgement that all licensees are responsible for compliance with applicable rules within the shared spaces.
 - Example should include security equipment and access, etc.



Commencement Inspection Requests

• 19 CSR 100-1.030(3)(C)

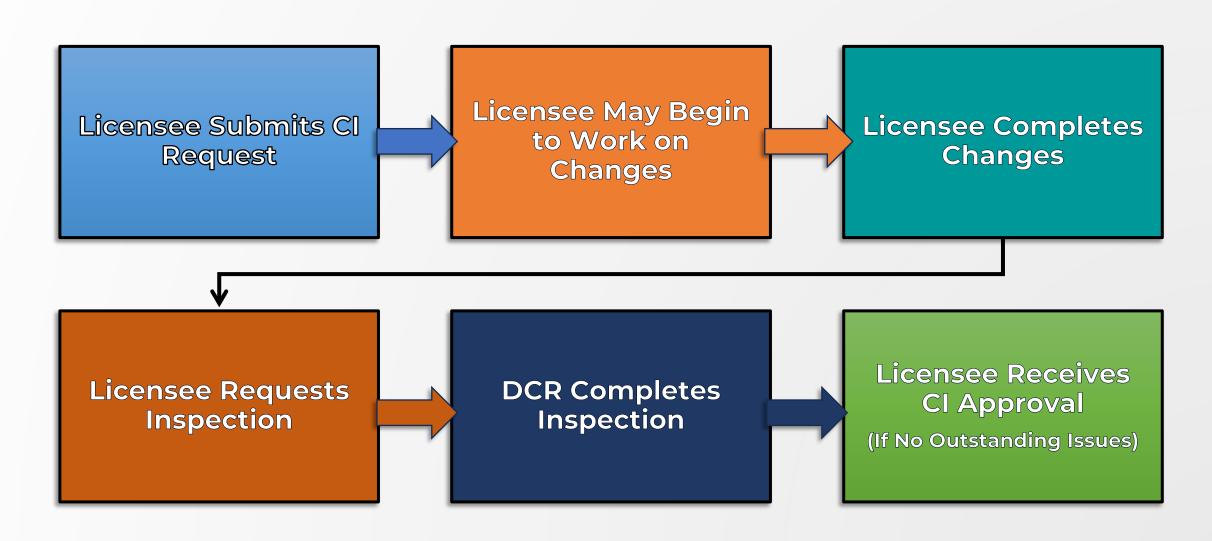
 Licensees are responsible for ensuring the approved spaces are secured while the unapproved spaces are being constructed.

• 19 CSR 100-1.030(3)(D)

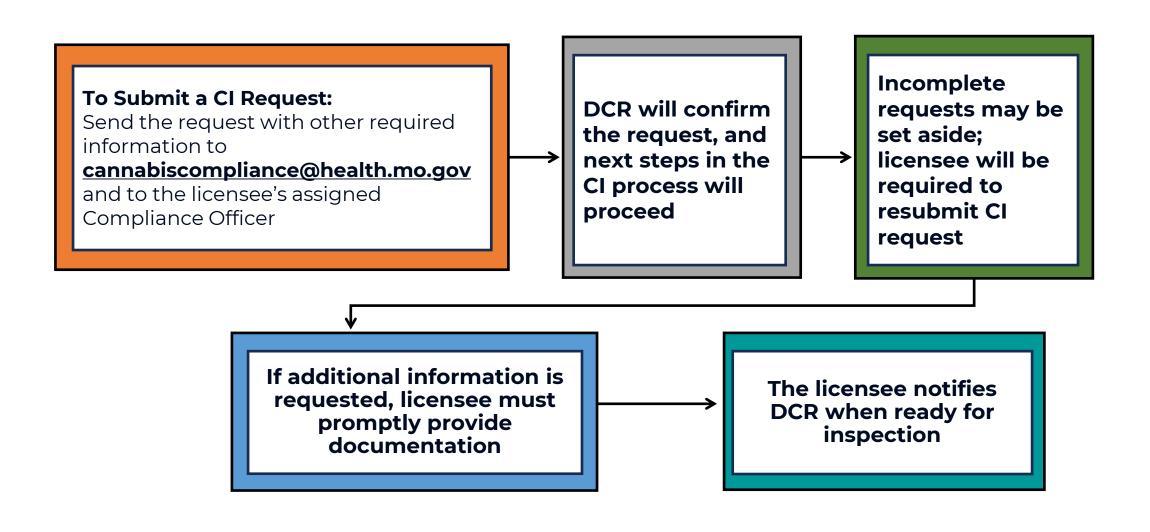
 Licensees may not commence any operations that are subject to a Commencement Inspection until DCR issues written approval to so.



Commencement Inspection(CI) Process



General CI Considerations



Commencement Inspection Requests

After inspection, the Compliance Officer will work with licensee to correct any outstanding compliance issues, as applicable



DCR will complete a review related to the CI and will provide a written approval to the licensee



If outstanding issues cannot be corrected within a reasonable timeframe following the inspection, licensee may be set aside and will be required to resubmit a CI request when outstanding issues have been resolved and licensee is ready to proceed.



Facility Employee Training

19 CSR 100-1.080

Licensee's Responsibility

Licensees must ensure all facility employees, contractors and volunteers are trained.

- All training shall be completed no later than one (1) week after an employee begins work at a facility.
- Training records must be maintained for at least 5 years.
- Licensees must make all training records available for review during inspections.
- Training records can be paper or electronic format.



19 CSR 100-1.080

Training Areas

As Applicable to Employee Duties:

- Use of security measures and controls that have been adopted by the licensee for the prevention or diversion, inversion, theft or loss of marijuana product
- Proper use of the state-wide track and trace system
- Department rules and guidance
- The safety and sanitation procedures of the facility
- All processes and procedures used by the facility

Procedures for responding to an emergency, including severe weather, fire, natural disasters and unauthorized intrusions

Note: If there is an update or modified SOP, training should occur no later than one week after that modification.



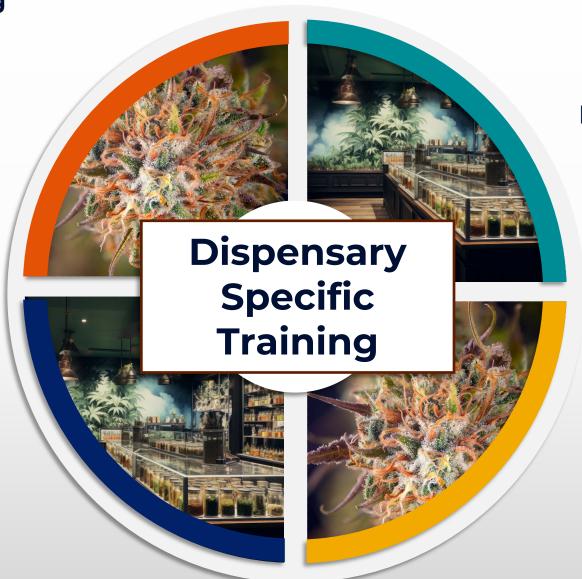


Track and Trace Training

- All facility staff are required to receive training on the proper use of the statewide track and trace system, as applicable to the employee's duties.
- Sign up for <u>Metrc Learn</u> training.
- Visit <u>Metrc Youtube</u> for quick informational videos on relevant topics.
- Visit the Metrc support center or call for assistance: 1-877-566-6506

Procedures for verifying purchase limitations of consumers, qualifying patients and primary caregivers.

Differences in the purported effects and effectiveness of strains of marijuana available for purchase at their dispensary and the methods of use.



Expected timeframes for individuals to feel the effects of marijuana product based on their chosen method of use.

Procedures for verifying a purchaser of marijuana product is of lawful age pursuant to this chapter.

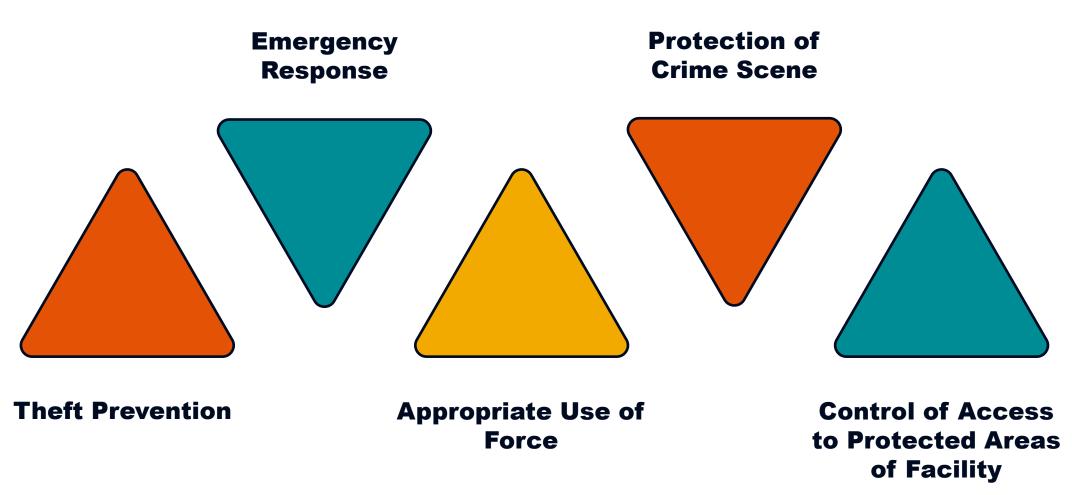




- Standards for maintaining the confidentiality of information related to the use of marijuana product.
- Procedures for verifying the identity and age of consumers, qualifying patients and primary caregivers.

Security Staff Training

The Security Manager and facility agents who provide security or third-party security must have completed trainings including the following subjects:



All Security Personnel are Required to Have:

Not fewer than eight (8) hours of training at the facility providing security services



Not fewer than eight (8) hours of classroom training in providing security services



Division of Cannabis Regulation

Mandatory Testing Failures





Failed Test Notification Requests

- 19 CSR 100-1.110(10)(A), marijuana product that fails mandatory testing will be placed on administrative hold by DCR.
- 19 CSR 100-1.010(2), administrative hold status "prohibits any activity with the marijuana product including waste, sale or transfer of the marijuana product until the hold is lifted."
- Administrative hold on failed marijuana products will be lifted upon proper notification of intent to DCR.

Failed Test Notification Requests

19 CSR 100-1.110(10)(B)

All marijuana product that fails mandatory testing must be reanalyzed, remediated or destroyed <u>within three</u>
(3) months of initial test failure.

19 CSR 100-1.110(10)(B)1

Before a Licensee can take any action with a marijuana product that failed mandatory testing, it must, **within fifteen (15) days of initial test failure**, notify DCR of the intent to proceed in one of the following ways:

- Reanalysis of previously tested sample.
- Remediation of the harvest or process lot through remediation actions specifically allowed by rule.
- Destruction of the harvest lot or process lot.
- Submission of a request to perform remediation not specifically allowed by rule.

Reanalysis

19 CSR 100-1.110(10)(B)2.A

- Reanalysis of the original sample may be performed by the testing facility that performed the initial analysis <u>or</u> a testing facility that did not perform the initial analysis.
- Notify assigned Compliance Officer and <u>cannabiscompliance@health.mo.gov</u> of the intent to reanalyze including:
 - Metrc package number
 - Date of initial testing failure
- If the sample <u>passes</u> reanalysis, a testing facility that did not perform the initial analysis or reanalysis may sample the lot and perform testing on the new sample in compliance with all rules for mandatory testing.

19 CSR 100-1.110(11)(E)

• A harvest or process lot that fails reanalysis **may not** be reanalyzed again but may be remediated one (1) time.





Remediation: Specifically Allowed by Rule

19 CSR 100-1.110(10)(B)

 Complete marijuana product remediation through a remediation process specifically allowed by rule.

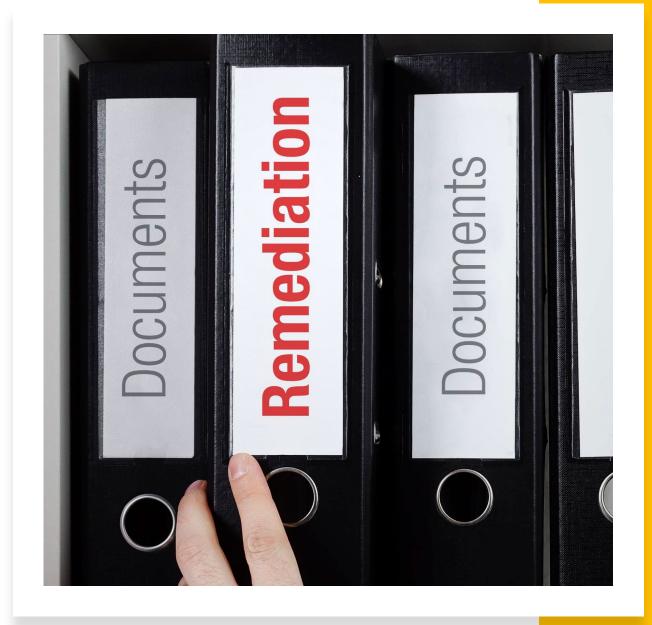
19 CSR 100-1.110(11)

- Approved remediation processes:
 - Failed microbial screening may be remediated through solvent-based extraction or processing, such as hydrocarbon, ethanol or carbon dioxide.
 - Failed residual solvent testing may be remediated by returning the product to a purging process within the facility.
 - Failed water activity testing may be remediated by:
 - Solvent-based extraction or processing
 - Additional drying or curing
 - Failed chemical residue screening may be remediated through solvent-based extraction or processing, such as hydrocarbon, ethanol or CO₂.



Remediation: Specifically Allowed by Rule (Continued)

- Notify assigned Compliance Officer and <u>cannabiscompliance@health.mo.gov</u> of the intent to remediate through an approved remediation process.
- The information should include:
 - The Metrc package number
 - Date of initial testing failure
 - Approved remediation method
 - Which licensee will be completing the remediation method



Remediation: Specifically Allowed by Rule (Continued)

19 CSR 100-1.110(10)(B)

 After a marijuana product has been remediated, the testing facility that performed the initial analysis or a testing facility that did not perform the initial analysis shall resample the lot and perform testing on that new sample in compliance with all rules for mandatory testing.

19 CSR 100-1.110(11)(F)

• A lot that fails remediation <u>may not</u> be remediated again but may be reanalyzed one (1) time.

19 CSR 100-1.110(6)(I)

• If a licensee is permitted under this rule to transfer a lot that has failed testing, the licensee must notify the licensee to whom the lot is sold or transferred of the failed test.





Remediation: Not Specifically Allowed by Rule

19 CSR 100-1.110(10)(B)2.D

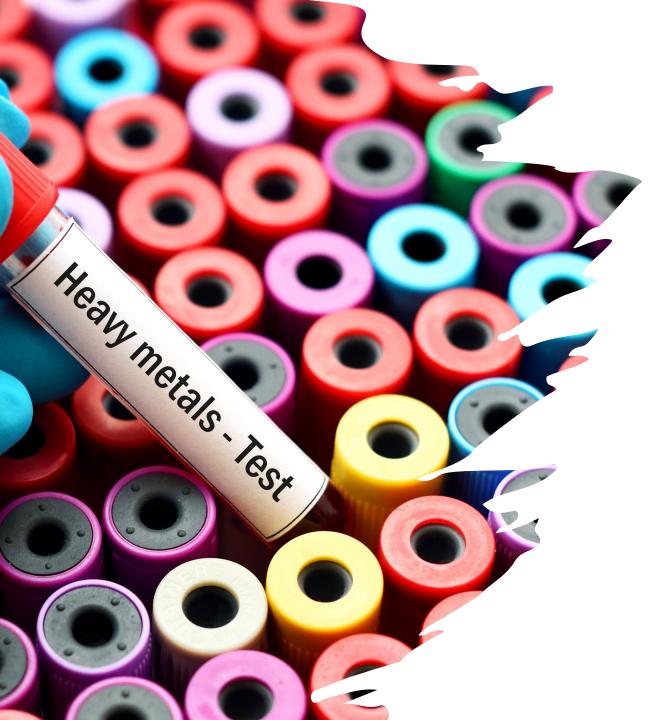
- If the remediation method is not specifically outlined by rule, a remediation request form is required to be submitted.
 - Submit to Compliance Officer and cannabiscompliance@health.mo.gov.
 - Link to request form: <u>https://health.mo.gov/safety/cannabis/pdf/remediation-request.pdf</u>
 - DCR is working to update these forms and provide forms for reanalysis, etc.
- The remediation request must be approved by DCR, in writing, prior to taking any remediation actions.

Destruction of Failed Marijuana Product

19 CSR 100-1.110(10)(B)2.C

- To destroy marijuana product that fails, notify assigned Compliance Officer and cannabiscompliance@health.mo.gov of the intent to destroy.
- The information should include
 - The Metrc package number
 - Date of initial testing failure,
 - Date and time of proposed destruction
 - The video camera names that will capture the two (2) angles of destruction
- Destruction of failed marijuana product shall comply with 19 CSR 100-1.150.





Heavy Metal Failures

19 CSR 100-1.110(10)(C)

- Marijuana product that fails mandatory testing for heavy metals shall be placed on administrative hold in Metrc and may not be remediated.
- The failed marijuana product can either be destroyed or reanalyzed, upon notification to DCR.

Inventory Control and Seed-to-Sale Tracking

19 CSR 100-1.130





Seed-to-Sale Tracking



19 CSR 100-1.130(1)(D)

 Each licensee shall use the state-wide track and trace system as its system of record to track marijuana product from seed or immature plant stage until the marijuana product is either purchased by a consumer, qualifying patient or primary caregiver; expended during testing; or destroyed.

19 CSR 100-1.100(4)(I)

 All marijuana product sold in Missouri shall have originated from marijuana grown and cultivated in a licensed cultivation facility located in Missouri.

19 CSR 100-1.170(2)(E)

 Any tetrahydrocannabinol, such as THC-A, Delta-8, or Delta-10, in a marijuana product manufactured by a manufacturing licensee shall only be derived from marijuana cultivated in Missouri by a licensed cultivator;

19 CSR 100-1.130(1)(E)

- All Marijuana product in a facility must be always traceable in the state-wide track and trace system.
- All immature plants at least eight (8) inches tall or eight (8) inches wide shall be tagged with traceability information.
- New packages are created when a marijuana changes categories, or it is incorporated into a different product.

State-Wide Track and Trace

Licensees shall record each day's inventory, including;

- Beginning
- Harvest
- Acquisitions
- Sales
- Disbursements

Metrc inventory must mirror physical inventory at the end of each day.



Manifest Errors

It is the responsibility of each licensee to maintain accurate system records when transferring product. Licensees are required to use the Transfer Hub in statewide track and trace for all transfers. (See MO Bulletin15: Transfer Hub for more information).

19 CSR 100-1.130(1)(M) requires all facility licensees to ensure the accuracy of information entered into the state-wide track and trace system, on a daily basis.



Change Testing Status Requests

Generally, a locked product indicates there may be a compliance issue. Actions that may lock a product include, but are not limited to:

- Misuse of production batches
- Creating an extra sample tag from a lot
- Adjusting extra sample tags down to zero instead of discontinuing them
- Sample taken and tagged from another sample tag
- Conducting R&D testing after a mandatory compliance panel has been completed
- Originating facility selects an Incorrect Lab Test Batch
 - By selecting the incorrect lab test batch, the testing facility may incorrectly test the product. Different tests have different failure limits which may cause the product results to be inaccurate.
- Testing Requirements document link: https://www.metrc.com/wp-content/uploads/2022/07/MO-Bulletin-14-Lab-Testing-Updates-04.4.22.pdf



State-Wide Track and Trace

All Licensees must ensure the accuracy of information entered in the state-wide track and trace system daily:

- Monthly inventory reports that reconcile physical inventory with inventory recorded in the state-wide track and trace system are submitted to the department
- Discrepancies in inventory are to be investigated by management reported to the department at **CannabisCompliance@health.mo.gov** within **24 hours.**
- Reduction in inventory due to suspected criminal activity by a facility agent shall be reported to the department at <u>CannabisCompliance@health.mo.gov</u> and appropriate law enforcement agency within **24 hours**.
- Errors involving consumer/patient allotments must be reported to <u>CannabisCompliance@health.mo.gov</u> and corrected within **24 hours** of being identified.

Reminders

- Inventory in Metrc must be reflective of physical inventory at the end of each day.
- Licensees must designate a facility agent for inventory control.
- Inventory records are maintained for at least 5 years.





Facility-Specific Permitted Activities

19 CSR 100-1

Division of Cannabis Regulation

Permitted Activities

Each facility type has individual activities that are deemed permissible for its specific facility type.



Cultivation Facilities

19 CSR 100-1.160

A cultivation licensee's authority to engage in the process of cultivating marijuana includes the ability to:

Acquire and transfer marijuana, marijuana seeds and clones from another cultivation facility

Acquire and transfer marijuana seeds

Acquire and transfer marijuana product from a manufacturing facility or dispensary facility

Cultivate marijuana



Cultivation Facilities

(Continued)

19 CSR 100-1.160

Process, package and store (on- or off-site) marijuana product

Transfer marijuana product to or from its own warehouse storage facility, another cultivation facility, manufacturing facility or dispensary facility

Transfer marijuana product to a testing facility

Sell marijuana product to another cultivation facility, manufacturing facility, dispensary facility or testing facility



Manufacturing Facilities 19 CSR 100-1.170

A manufacturing licensee's authority to engage in the process of manufacturing marijuana-infused products includes the ability to;

Acquire and transfer marijuana from a cultivation facility

Acquire and transfer marijuana product from another manufacturing facility to further process

Acquire and transfer marijuana product from a dispensary facility

Process and store (on- or off-site) marijuana product



Manufacturing Facilities

(Continued)

19 CSR 100-1.170

Manufacture and package marijuanainfused products and prerolls

Transfer marijuana product to or from its own warehouse storage facility, another manufacturing facility, cultivation facility or dispensary facility

Transfer marijuana product to a testing facility

Sell marijuana product to another manufacturing facility, cultivation facility, dispensary facility or testing facility



Dispensary Facilities 19 CSR 100-1.180

A dispensary licensee's authority to engage in the process of dispensing marijuana

Acquire and transfer marijuana, marijuana seeds, clones and prerolls from a cultivation facility

Acquire and transfer marijuana-infused products and prerolls from a manufacturing facility;

Acquire and transfer marijuana product from another dispensary facility

Create and sell prerolls



Dispensary Facilities

(Continued)

19 CSR 100-1.180

Package and store (on- or off-site) marijuana product and drug paraphernalia used to administer marijuana product

Transport and sell or distribute marijuana product and drug paraphernalia to another dispensary facility, manufacturing facility, cultivation facility, testing facility or individuals authorized to purchase marijuana product for personal or medical use

Transfer marijuana product to or from its own warehouse

Microbusinesses 19 CSR 100-1.190

Microbusiness Dispensary Licensees

- Licensed to engage in the process of dispensing marijuana product for medical or adult use
- Shall only acquire marijuana product from a microbusiness wholesale facility or another microbusiness dispensary facility

Microbusiness Wholesale Licensees

- Licensed to engage in the process of cultivating and manufacturing marijuana product for medical or adult use
- May only transfer its products to a testing facility, transportation facility, microbusiness dispensary facility or to another microbusiness wholesale facility



Advertisement

19 CSR 100-1.010 Definitions

(3) "Advertisement" means any dissemination of information by print, audio or video means, whether through the media or otherwise, including but not limited to billboards, radio, television, motion pictures, newspapers, internet, email, texting, website, mobile applications, magazines or similar publications or other printed or graphic matter, or any electronic means, except that the term shall not include;

- (A) Any packaging or label affixed to packaging of marijuana product; and
- (B) Any editorial in any periodical or publication or newspaper for the preparation or publication of which no money or other valuable consideration is paid or promised, directly or indirectly, by or on behalf of any entity subject to these regulations.



Signage and Advertisement

19 CSR 100-1.100 Facilities Generally

- (5) Signage and advertising must comply with the following:
 - (B) No advertisement of marijuana may contain:
 - Any representation that is false or misleading in any way;
 - 2. Any statement representing that the use of marijuana has curative or therapeutic effects or tending to create an impression that it has curative or therapeutic effects unless such statement has been evaluated and approved by the Food and Drug Administration;
 - 3. Any content that is attractive to children, including but not limited to the shape or any part of the shape of an animal or fruit, including realistic, artistic, caricature or cartoon renderings, and artistic, caricature or cartoon renderings of the shape or any part of the shape of a human; or
 - 4. Any statement concerning a brand of marijuana that is inconsistent with any statement on the labeling;







MISSOURI DEPARTMENT OF

HEALTH & SENIOR SERVICES

Transportation and Transfer Of Marijuana Product

19 CSR 100-1.140

Division of Cannabis Regulation

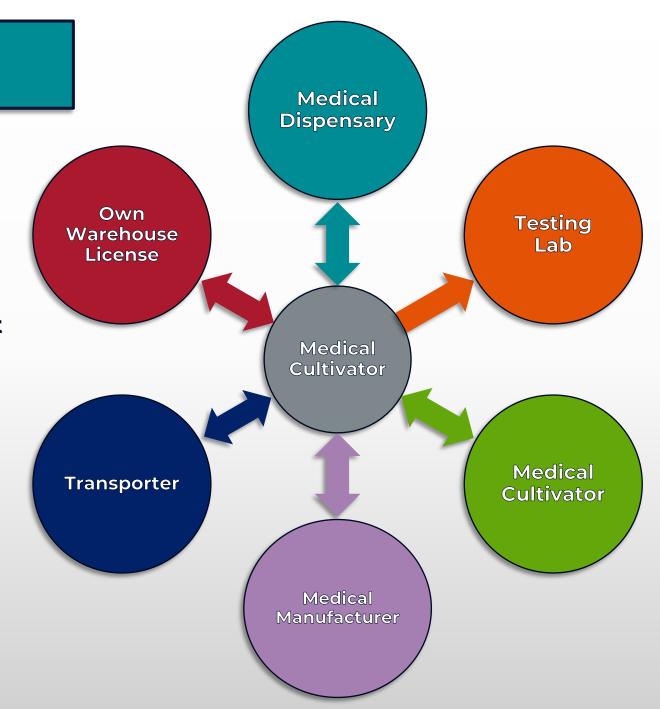
Permitted Medical Cultivator Transport and Transfers

19 CSR 100-1.140(2)(B)1

Applies to All Medical Facility Licensees

- A medical facility licensee shall be allowed to transfer marijuana product between facilities:
 - From a medical facility to another medical facility or testing facility.

19 CSR 100-1.160(1)(A)-Medical Cultivator: See Diagram



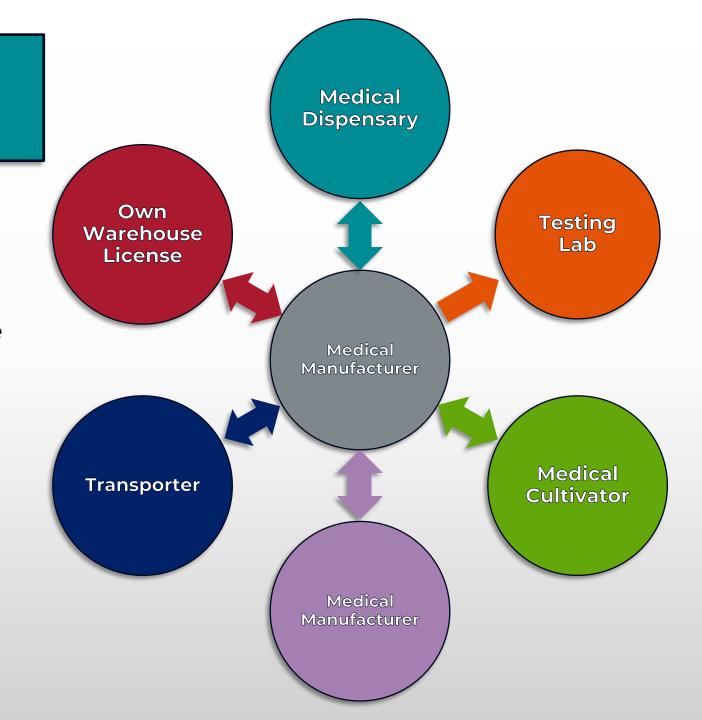
Permitted Medical Manufacturer Transport and Transfers

19 CSR 100-1.140(2)(B)1

Applies to All Medical Facility Licensees

- A medical facility licensee shall be allowed to transfer marijuana product between facilities:
 - From a medical facility to another medical facility or testing facility.

19 CSR 100-1.170(1)(A)-Medical Manufacturer: See Diagram



Permitted Medical Dispensary Transport and Transfers

19 CSR 100-1.140(2)(B)1

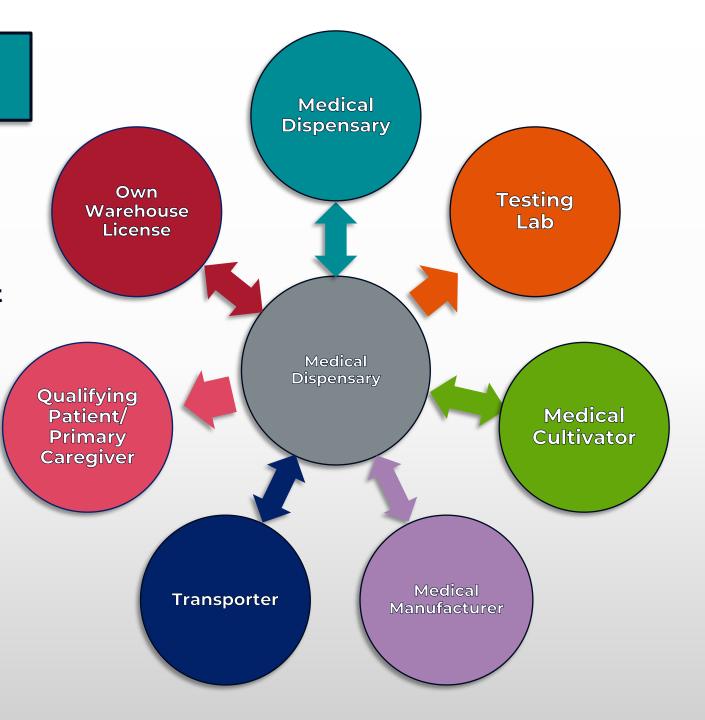
Applies to All Medical Facility Licensees

- A medical facility licensee shall be allowed to transfer marijuana product between facilities:
 - From a medical facility to another medical facility or testing facility.

19 CSR 100-1.140(3)(B)1 – Medical Dispensary

 A medical dispensary facility licensee shall be allowed to deliver marijuana product to qualifying patients and primary caregivers.

19 CSR 100-1.180(1)(A)-Medical Dispensary: See Diagram

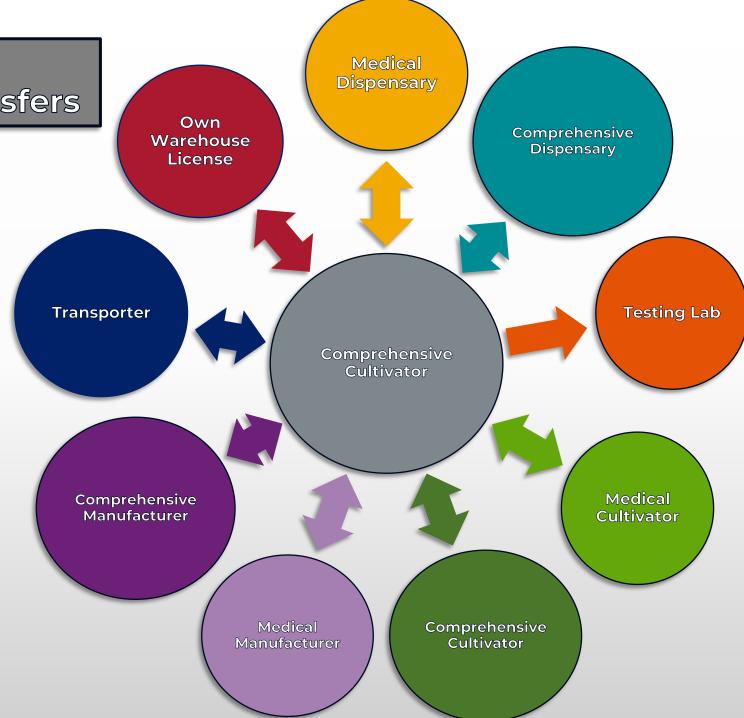


Permitted Comprehensive Cultivator Transport and Transfers

19 CSR 100-1.140(2)(B)2 - Applies to all Comprehensive Facilities

- A marijuana facility licensee shall be allowed to transfer marijuana product between facilities:
 - From a comprehensive facility to another comprehensive facility, medical facility or testing facility.

19 CSR 100-1.160(1)(A) – Comprehensive Cultivation: See Diagram

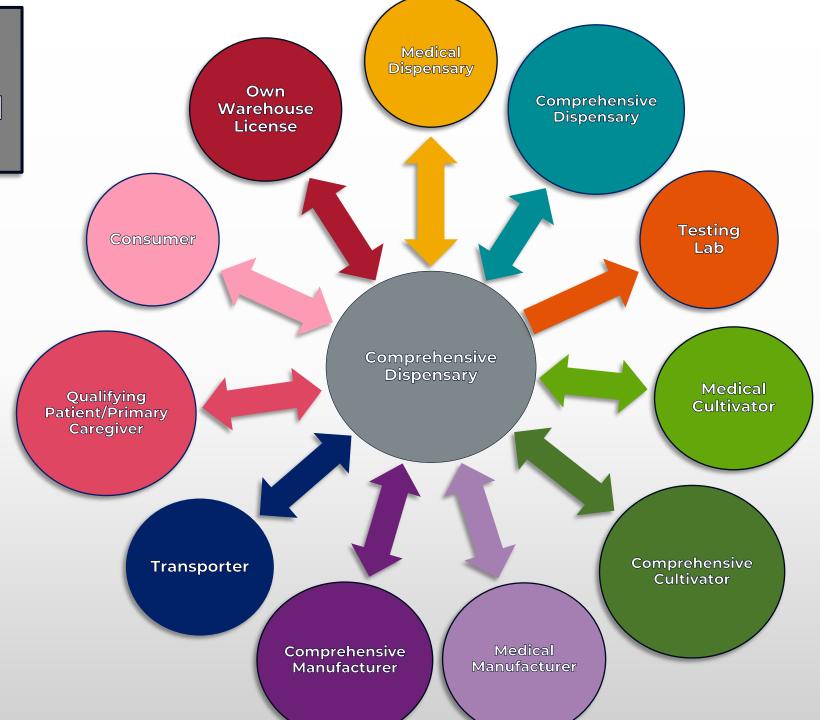


Permitted
Comprehensive
Dispensary Transport and
Transfers

19 CSR 100-1.140(3)(B)2 – Comprehensive Dispensary

 A dispensary facility licensee shall be allowed to deliver marijuana product to consumers, qualifying patients and primary caregivers.

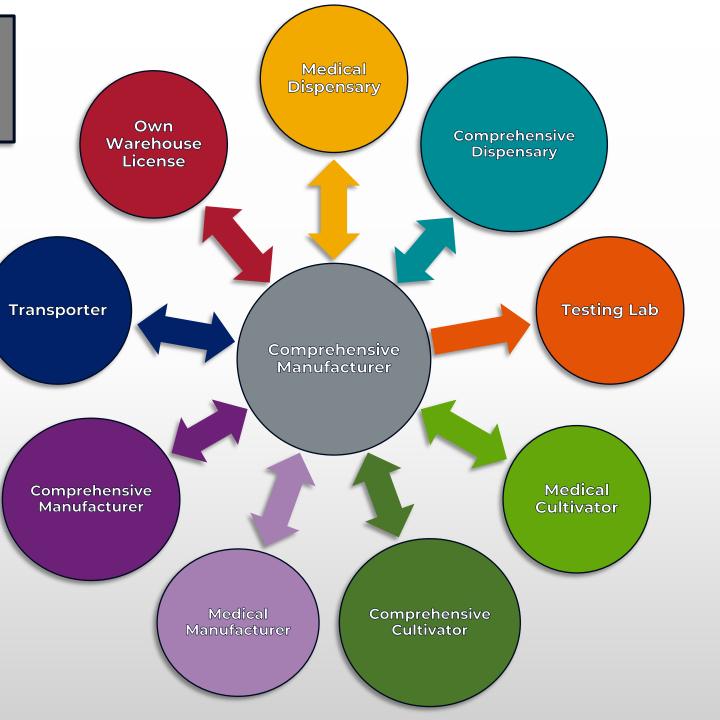
19 CSR 100-1.180(1)(A) – Comprehensive Dispensary: See Diagram



Permitted Comprehensive Manufacturer Transports and **Transfers**

19 CSR 100-1.170(1)(A) - Comprehensive

Manufacturer: See Diagram



Permitted Microbusiness Dispensary Transport and Transfers

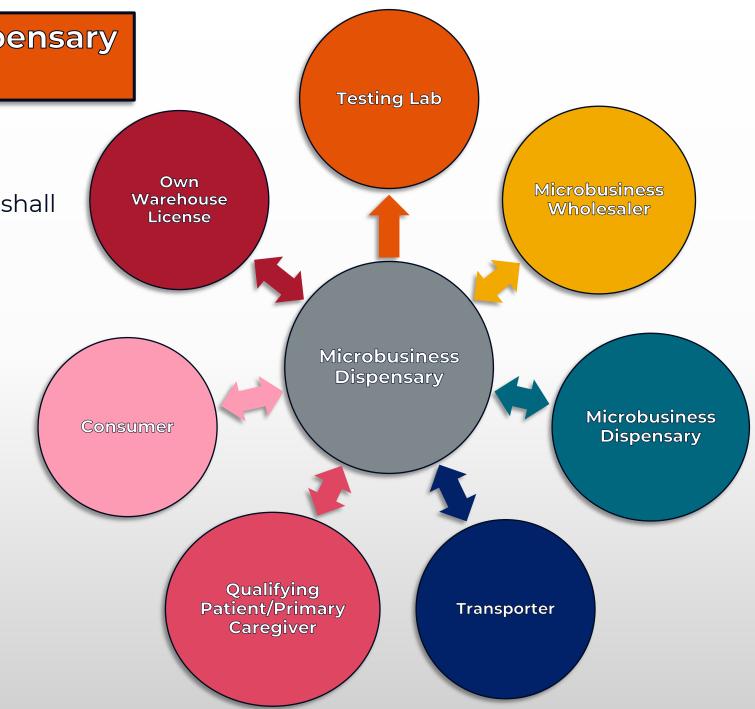
19 CSR 100-1.190(2)(B) - Microbusiness Dispensary

 Microbusiness dispensary licensees shall only acquire from a microbusiness wholesale licensee or another microbusiness dispensary licensee.

19 CSR 100-1.140(3)(B)2 – Microbusiness Dispensary

 A Microbusiness dispensary facility licensee shall be allowed to deliver marijuana product to consumers, qualifying patients and primary caregivers.

19 CSR 100-1.180(1)(A) - Microbusiness Dispensary: See Diagram



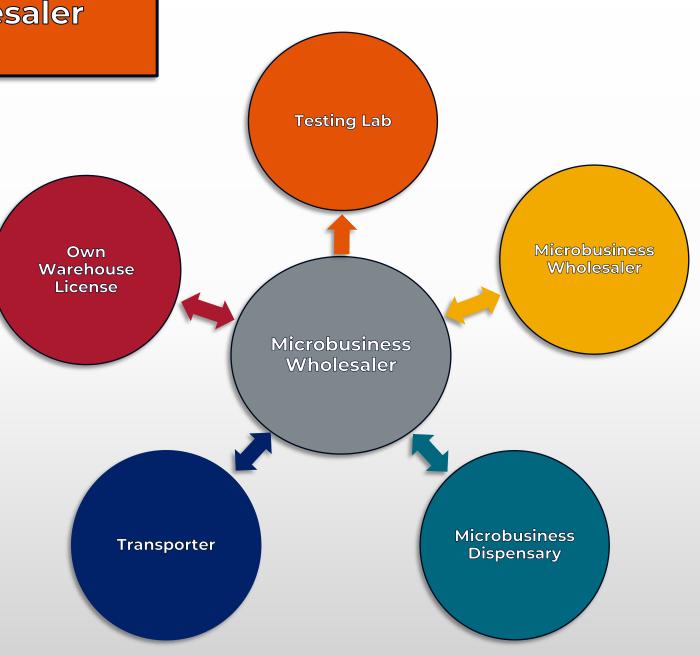
Permitted Microbusiness Wholesaler Transport and Transfers

19 CSR 100-1.190(3)(B) - Microbusiness Wholesaler

 Microbusiness wholesale licensee may only transfer to a testing facility, transportation facility, microbusiness dispensary licensee or to another microbusiness wholesale licensee.

19 CSR 100-1.160(1)(A) – Microbusiness Wholesaler Cultivation: See Diagram

19 CSR 100-1.170(1)(A) – Microbusiness Wholesaler Manufacturing: See Diagram



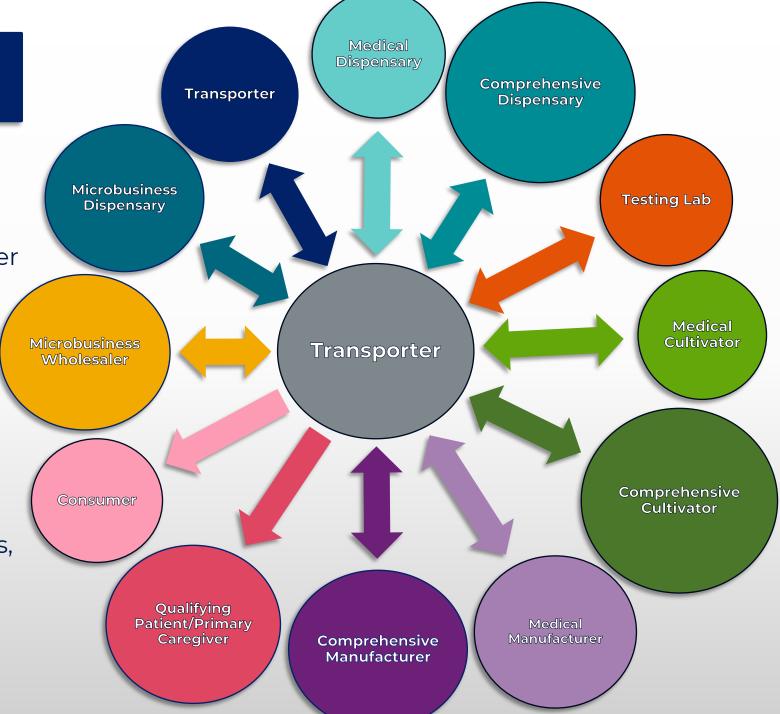
Permitted Transporter Transport and Transfers

19 CSR 100-1.140(2)(B) - Applies to all transportation facilities

 A transportation certificate holder shall be allowed to transfer marijuana product between facilities: See Diagram

19 CSR 100-1.140(3)(B) – Applies to all transportation facilities

 Transportation certificate holder shall be allowed to deliver marijuana product to consumers, qualifying patients and primary caregivers: See Diagram



Permitted Testing Transport

19 CSR 100-1.140(2)(B) - Applies to all testing facilities: See Diagram

- A medical or marijuana facility licensee shall be allowed to transfer marijuana product between facilities as follows:
 - From a medical facility to another medical facility or testing facility.
 - From a comprehensive facility to another comprehensive facility, medical facility or testing facility.
 - From a microbusiness facility to another microbusiness facility or testing facility.

19 CSR 100-1.140(2)(C) – Applies to all testing facilities: See Diagram

 Testing licensees may only transport marijuana product that they intend to test.





Licensee Notification and Reporting

19 CSR 100-1.100(6)

Rule Requirement

Licensees have a duty to keep the department apprised of certain information.

Failure of a licensee to report required information to the department may result in administrative penalties, to include a fine of up to ten thousand dollars (\$10,000), suspension or revocation of the license.



Required Notifications

19 CSR 100-1.100(6)

19 CSR 100-1.100(6)(A)

Licensees have a continuing duty to provide the department with up-to-date contact information.

19 CSR 100-1.100(6)(C)

Licensees shall notify the department within five (5) days of the initiation and conclusion of any legal proceedings, government investigations or any other activity that would impair the licensee's ability to operate.

19 CSR 100-1.100(6)(D)

Licensees shall notify the department when a facility agent has been terminated for misconduct related to handling of marijuana product.

19 CSR 100-1.100(6)(E)

Licensees shall notify the department within twenty-four (24) hours following the occurrence of an event that affects the health and safety of the facility or its employees.

Required Notifications (Continued) 19 CSR 100-1.100(6)

19 CSR 100-1.100(6)(F)

Licensees shall notify the department within twenty-four (24) hours of discovery of any theft or attempted theft of marijuana product.

19 CSR 100-1.100(6)(G)

Licensees shall notify the department **within twenty-four (24) hours** of discovery of any criminal misconduct of an employee, contractor, owner or volunteer.

19 CSR 100-1.100(6)(H)

Cultivation licensees shall notify the department before changing its cultivation practice (indoor, outdoor or greenhouse) or modifying the ratios of cultivation practices it uses.

19 CSR 100-1.100(6)(I)

After the department approves a change in location, the licensee shall request a commencement inspection and notify once ready for physical inspection

19 CSR 100-1.100(6)(K)

Licensees shall notify the department in writing prior to initiating a facility update that would be subject to **19 CSR 100-1.090**.



How to Notify DCR and Report Required Information

To properly notify DCR, licensees shall email the DHSS.DCR-Compliance inbox and their assigned Compliance Officer.

DHSS.DCR-Compliance email CannabisCompliance@health.mo.gov

Webpage: https://health.mo.gov/safety/cannabis/



Division of Cannabis Regulation

Bureau of Investigation and Enforcement (BIE)





Investigations

- Investigations may begin through different ways:
 - Complaint
 - Complaint form
 - Email
 - Phone
 - Compliance Issues
 - Physical inspections
 - Document reviews
 - State-wide track and trace system reviews
 - Referrals
 - Law Enforcement
 - Other Regulatory Bodies
 - Industry



Complaints

19 CSR 100-1.030(1)



- Complaint form can be found on Division of Cannabis Regulation (DCR) website.
- DCR will determine if a complaint warrants further investigation.
- If it warrants further investigation, DCR will advise the licensee of the nature of the allegations in the complaint and provide the licensee with the opportunity to respond.
- Current and former employees, contractor, owners and volunteers of a licensee who, in good faith, report potential rule violations to the department may not be subject to retaliation of any kind by the licensee because of their report.



Inspections and Investigations

19 CSR 100-1.030(2)

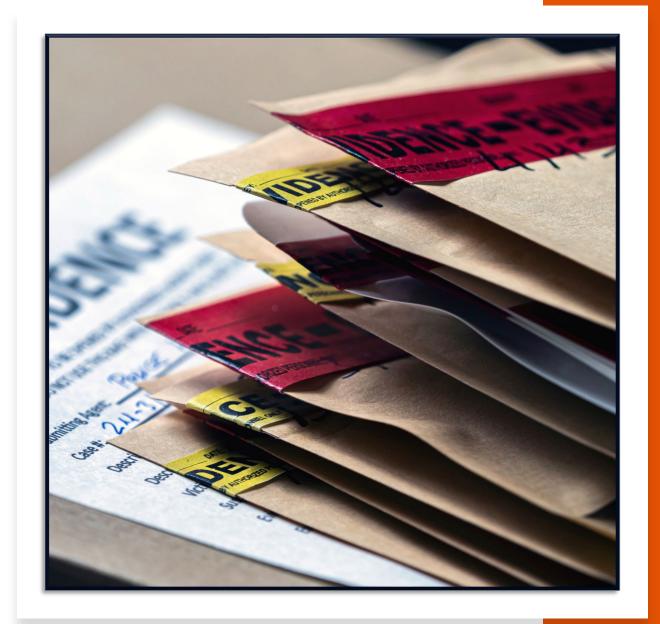
- DCR may conduct an inspection or investigation at any time.
 - Inspection may be a document review, physical inspection or review of statewide track and trace system, including third party records.
 - Once notified of an investigation, Licensees and required to preserve all records of any type related to the investigation at the expense of the licensee.
 - Records include video camera recordings and facility access control records.
 - <u>Licensees are required to preserve records until receiving notice that the investigation is concluded.</u>
- Licensees are required to cooperate in a DCR investigation.

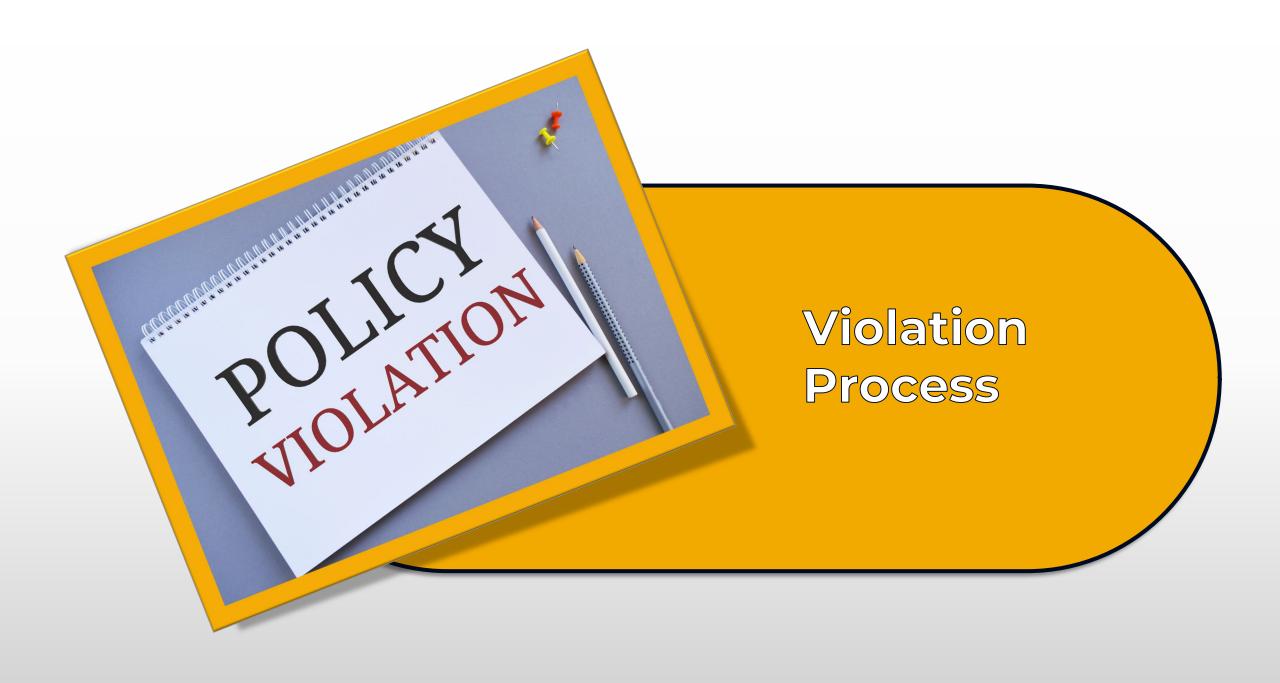
Inspections and Investigations (Continued)

- Licensees must provide documents or records requested as part of an inspection/investigation within seven (7) days unless additional time is requested and granted prior to the deadline.
 - DCR may fine \$5000 for every day the documents are not provided after the deadline.
 - DCR may request to interview any employees, contractors, owners or volunteers.
 - Licensee is required to arrange interviews to occur as soon as possible, but **not** later than seven (7) days after the request is made.

DCR Notices

- Notices are issued to the individual identified by the licensee as the designated contact in the Online Registry Portal (Complia).
- Notices are sent by email to the email address provided by the designated contact for the licensee.





Violation Process

19 CSR 100-1.030(4)

- Initial Notice of Violation (INOV)
- Final Notice of Violation (FNOV)
- Notice of Violation (NOV)
 - How the licensee violated DCR rule.
 - Remedial actions DCR expects the licensee to take.
 - Licensee or certification may be suspended or fined if specified remedial actions are not taken or the violations are not cured FNOV.
- Licensee must notify DCR in writing upon completion of all remedial actions.



Violation Process (Continued)

19 CSR 100-1.030(4)(B)



- INOV 15 days
 - Must request additional time if needed prior to the deadline.
- FNOV 30 days
- Multiple Initial Notice of Violation (INOVs)
 - Receive an INOV for more than three (3) rules in a 12-month period.
 - Receive more than one INOV for the same rule violation in 12-month period.
- Licensee may be required to:
 - Acquire accreditation or certification from quality management system (QMS); or
 - Be subject to an audit of the licensee's processes or practice relevant to the violations by a third-party auditor.
 - Both QMS and third-party auditor will be chosen by DCR at expense of licensee.





Penalties



19 CSR 100-1.020(3)

- DCR has the authority to take enforcement actions against a licensee found in violation of 19 CSR 100-1 or Article XIV, including:
 - Limitation or restriction of certification or license.
 - Fines up to the amount of average daily gross receipts of the previous calendar month.
 - Revocation/suspension/non-renewal of the license or certification.
 - Orders to immediately cease or suspend operations.

Limitation or Restriction

19 CSR 100-1.020(3)(A)1

- DCR may limit or restrict licensee from otherwise permitted activities, including but not limited to purchasing, possessing, producing, selling and/or distributing marijuana.
- The limitation or restriction will remain in place until the licensee receives notice from DCR that the limitation or restriction has been lifted.





Fines

19 CSR 100-1.020(3)(B)

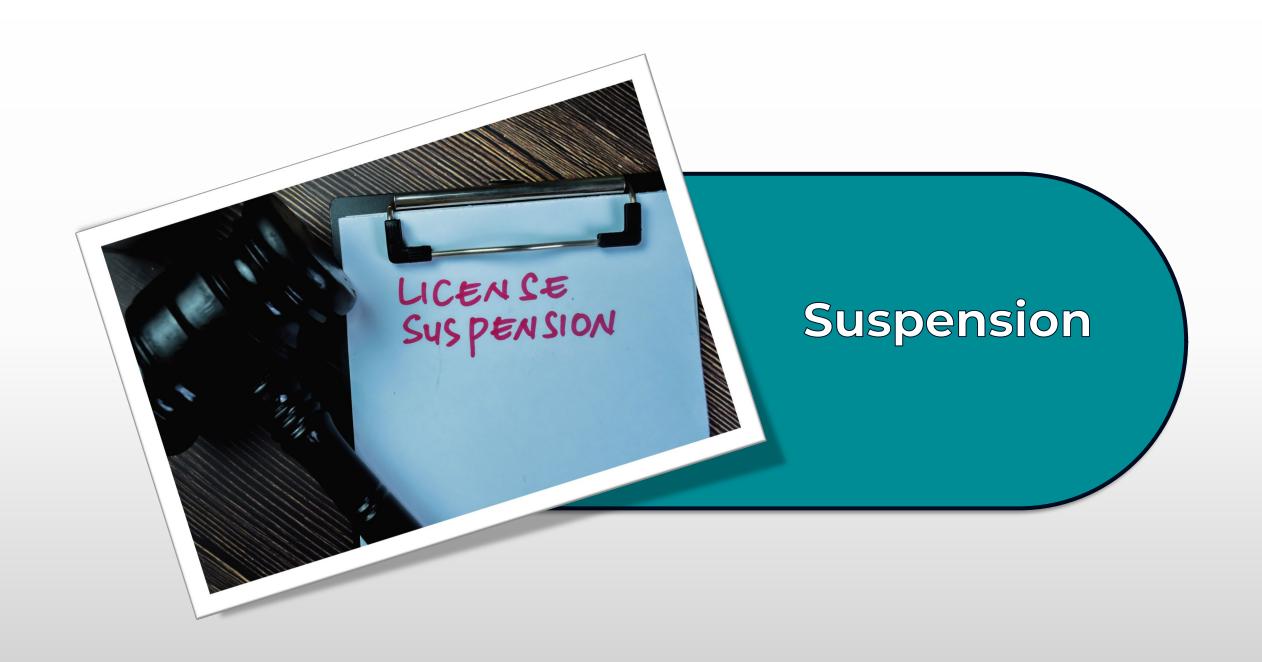
- Fines up to an amount equal to the average daily gross receipts of the previous calendar month of the facility may be assessed for each day the licensee is in violation.
- Fines do not bar DCR from administering additional penalties and enforcement actions.
- A licensee may be required to provide the average daily gross receipts for the previous calendar month of the facility.
 - Licensees must account for the marijuana product that is transferred within an entity or exchanged with another licensee when reporting the average daily gross receipts.
 - The average daily gross receipts multiplied by the number of days a licensee is in violation of rule equals the maximum fine amount that DCR may access.



Fines (Continued)

19 CSR 100-1 outlines specific areas of compliance with fines, for example:

- Failure to fulfill document or records request within timeframe (19 CSR 100-1.030(2)(B)3.A) \$5000/day.
- Failure to report required information (19 CSR 100-1.100(6)) up to \$10,000.
- Failure to comply with sampling requirements or manipulation of samples (19 CSR 100-1.110(6)(H)) – up to \$100,000.
- Failure to comply with the statewide track and trace system requirements or intentional misuse or falsification of tracking data (19 CSR 100-1.130(2)(E)2) – up to \$50,000.



Notice of Pending Suspension

19 CSR 100-1.020(3)(G)

- The notice contains the basis for a pending suspension.
- Suspension does not take effect for at least 30 days from the date the notice is sent.
- The notice will allow a licensee 30 days to:
 - Cure deficiencies listed in the notice and/or provide a response and records or information to explain why the licensee should not be suspended.
- At the end of the 30-day timeframe, DCR will determine whether or not the deficiencies have been cured.
 - If DCR is satisfied with the response and records provided by the licensee, it will issue a notice that the notice of pending suspension is satisfied.
 - If DCR is **not** satisfied with the response and records provided by the licensee, it will order immediate suspension of the license.



Notice of Suspension



- Suspension of a license requires a licensee to cease all operations related to the license immediately, including activities within the facility or affiliated with the licensee. Suspended activities include transferring or accepting marijuana product and entering information in the state-wide track and trace system, Metrc.
- When DCR orders a licensee to suspend operations, a licensee must immediately secure all marijuana product in the facility and may not enter the facility unless approved by DCR prior to entry.
- A suspended licensee must maintain compliance with all applicable requirements outlined within 19 CSR 100-1, facility security requirements, such as electronic video monitoring and access controls requirements.



Revocation

Notice of Pending Revocation

19 CSR 100-1.020(3)(G)

- The notice contains the basis for a pending revocation.
- Revocation does not take effect for at least 30 days from the date the notice is sent.
- The notice will allow a licensee 30 days to:
 - Cure deficiencies listed in the notice and/or provide a response and records or information to explain why the licensee should not be revoked.
- At the end of the 30-day timeframe, DCR will determine whether or not the deficiencies have been cured.
 - If DCR is satisfied with the response and records provided by the licensee, it will issue a notice that the notice of pending revocation is satisfied.
 - If DCR is not satisfied with the response and records provided by the licensee, it will order immediate revocation of the license.



Notice of Revocation

 The Licensee and its facility will no longer be authorized to possess or complete any activity related to marijuana product. Possession of a controlled substance without Department approval may subject the associated individuals to criminal violations. See § 579.020, RSMo.

Notice of Revocation

(Continued)

19 CSR 100-1 outlines specific areas of rule that call for restriction, suspension and/or revocation, for example:

- An ownership dispute that impairs the operations of the facility or Department review of an application (19 CSR 100-1.070(1)(H)). Restriction, Suspension or Revocation (if restricted/suspended for longer than 1 year).
- A licensee loses control of approved location, facility or license (19 CSR 100-1.100(4)(F)).
 Restriction or Suspension.
- Failure to report required information (19 CSR 100-1.100(6)). Suspension or Revocation.
- Violation of sampling requirements or manipulation of samples (19 CSR 100-1.110(6)(H)).
 Suspension or Revocation.
- Failure to comply with the statewide track and trace system requirements or intentionally misuses or falsifies state-wide track and trace system tracking data (19 CSR 100-1.130(2)(E)2) Restriction, Suspension or Revocation.

Immediate Order of Suspension/Revocation:

Except where there is a credible and imminent threat to public safety, the revocation or suspension will not take effect until thirty (30) days from the date the notice is sent.

19 CSR 100-1.020(3)(G)1

- If there is a credible and imminent threat to public safety, the department may order a licensed facility to immediately suspend all or part of its operations, including placing an administrative hold on marijuana product, until the threat has been eliminated.
- An imminent threat to public safety includes, but is not limited to:
 - A dangerous condition at the facility that is likely to harm employees or the public;
 - A credible report, such as from law enforcement, that diversion or inversion of marijuana product is occurring at the licensed facility; and/or
 - A credible report that a facility's practices are permitting marijuana product to enter the regulated market without being compliantly tested.



Event Participation

19 CSR 100-1.020(3)(E)

- A licensee that organizes an event or partners with another entity to promote an event may be subject to the penalties in 19 CSR 100-1.020(3)(A) for any violations of 19 CSR 100-1 that occur at that event.
- Licensees are responsible for ensuring all participants, including outside parties, are aware of what is allowed and to take measures to prevent, address and report violations.
- There is no scenario where a licensee or agent ID holder working for a licensee may give away, sell or otherwise distribute marijuana to anyone unless they are doing so in an approved area of the dispensary facility and each individual person and product is entered into Metrc appropriately.



Facility Agent

Facility Agent

19 CSR 100-1.070(2)

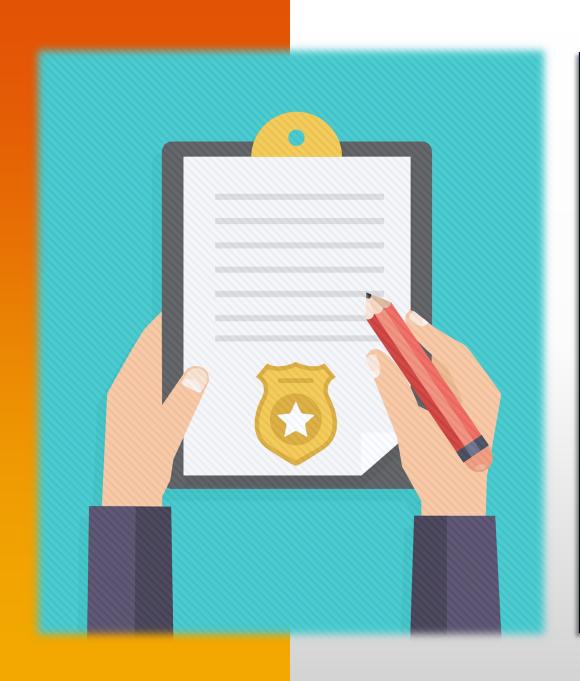
- A facility agent is an individual who holds an agent identification card issued by the department.
- ID cards are valid for 3 years and are renewable.
- Facility agents must be twenty-one (21) years old.
 - Individuals under twenty-one (21) who possess a facility agent identification card prior to the effective date of the final rule may remain facility agents.
- · Required to have an agent ID card
 - All employees, contractors, owners having access to a medical or marijuana facility, and volunteers of a medical or marijuana facility must obtain an agent identification card from the department <u>before beginning</u> employment, work or volunteer services at a licensed or certified facility.

Facility Agent (Continued)

- Not required to have an agent ID card
 - An individual performing maintenance work (such as plumbing) or other similar work for no more than fourteen (14) days in a calendar year are not required to have an agent ID card.
 - Does not include individual with tasks related to testing, transporting, growing, manufacturing or dispensing marijuana product at any licensed or certified facility.
 - The licensee is responsible for supervising such individuals while they are in the facility.

Facility Agent (Continued)

- Facility agents must have ID cards at all times while performing work in facility or on behalf of licensee as follows:
 - · Agent ID card must be visible and on their person.
 - · Government issued ID: must be on their person.
- Facility agents must keep the department informed of:
 - Current contract information
 - Agents must notify the department within fourteen (14) days of changes to their name, address or email address.
- · Facility agents must agree to receive department emails.



Facility Agents

Inspection/Investigation

19 CSR 100-1.030(2)(A)

 DCR may conduct an investigation related to an individual cardholder if the department has reason to believe the individual has or is violating any rule in this chapter or provision of Article XIV that could affect the individual's right to continue holding the authority granted by the department.

Agent ID Revocation

19 CSR 100-1.070(2)(J)

- Reasons for Revocation
 - Submission of deceptive, misleading, incorrect, incomplete or false agent ID application.
 - Fraudulent use of an agent ID card.
 - Selling, distributing, transferring in any manner or giving marijuana product to any unauthorized individual or entity, or an amount of marijuana product not authorized by law.
 - Tampering with or falsifying video recordings or equipment, point of sale systems or records, the state-wide track and trace system or records, or any other facility records, whether at the direction of a licensee or otherwise.

Agent ID Revocation (Continued)

19 CSR 100-1.070(2)(J)

- Reasons for Revocation(Continued)
 - Failing to comply with the state-wide track and trace system requirements.
 - Violation of any requirement in 19 CSR 100-1.
 - Prohibited by law from holding an agent ID card.
 - If the agent has committed theft or other criminal offense, whether or not a criminal charge has been filed, in the performance of the functions or duties of the facility agent.
 - Refusal to cooperation with DCR investigation.



Division of Cannabis Regulation

Bureau of Investigation and Enforcement (BIE)



Division of Cannabis Regulation Compliance Assessment Unit

Product Compliance Team



Packaging and Labeling Responsibility

- Pursuant to 19 CSR 100-1.120, licensees that produce the final marijuana product are responsible for mandatory testing, packaging and labeling to ensure the health and safety of patients and consumers.
- The licensee that submits the final packaging for Division of Cannabis Regulation (DCR) review as required by 19 CSR 100-1.120(2)(A) is responsible for compliant packaging and labeling.

Item Approval History

- DCR implemented the Item Approval process on September 1, 2023, per **19 CSR 100-1.120(2)** for final marijuana product.
- This process requires licensees to submit all marijuana product designs, packaging designs and label designs to DCR for a compliance review with **19 CSR 100-1.120(1)**, prior to use.
- The Item Approval process is in place to ensure products and packaging are designed in a manner that protects public health.
- In working through the Item Approval process and considering feedback from licensees, DCR continues to identify areas that will improve the process and allow DCR and licensees to gain efficiencies.

• As of June 17, 2024:

• Submitted: 76,282

Reviewed: 44,119

• Approved: 33,808

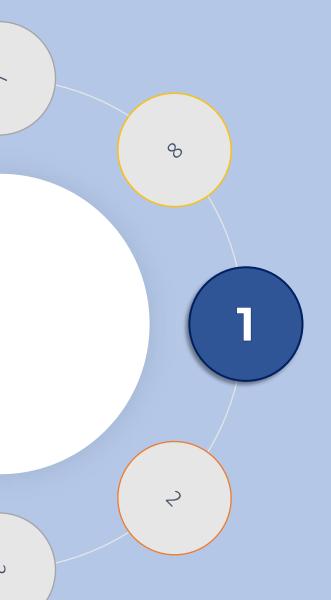
Denied: 10,311

Item Approval Overview

- Item Approval process is to ensure compliant packaging and labeling for final marijuana product.
- Prior to use licensee submits item for review using the state-wide track and trace system (Metrc) and DCR email.
- Within 30 days of submission DCR reviews submission to determine if complete.
 - If incomplete DCR will identify reasons the submission is incomplete and denies item.
 - If complete DCR will review submission for compliance with 19 CSR 100-1.120(1).
- Within 60 days of submission DCR reviews complete submission and approves or denies item.
 - If approved DCR will issue an approval number for the marijuana product, packaging and label design, as a whole.
 - If denied DCR will email the licensee to list the deficiencies.
- To assist with processing times, if a licensee deletes an "in review" item, DCR encourages
 licensees to contact the Product Compliance Team to notify that the item has been removed.

Item Approval Overview (Continued)

- The creation of a new item in the "Final Packaging" categories will cause automatic submission of the item for approval. After an item is created and approved, a licensee continues to use the item in Metrc each time the marijuana product is produced by selecting the appropriate "final packaging" category that has already been approved for the product.
 - For example: Green Apple gummies are produced by a licensee in the final marijuana product stage and have passed mandatory testing, the licensee selects "Green Gummies" item in the "final packaging" category that has already been created and approved through the Item Approval process for the product.



Process 01

Types of Submissions:

Non-template-based items

- An "actual item" to be used by the licensee.
- Does not reference approved template.
- Stand-alone submission.



Types of Submissions:

Template Item

Not an "actual item" to be used by the licensee. Template design for items to be based, which uses certain identifiers to verify compliance.

Example: Item name must start with "TEMPLATE", Best if used by date: XX/XX/XXXX, D9-THC: ##.# mg / serving, Flavor: [Flavor / Strain]

Allows licensee to submit an item for review to ensure compliance and reference for future template-based item submissions.





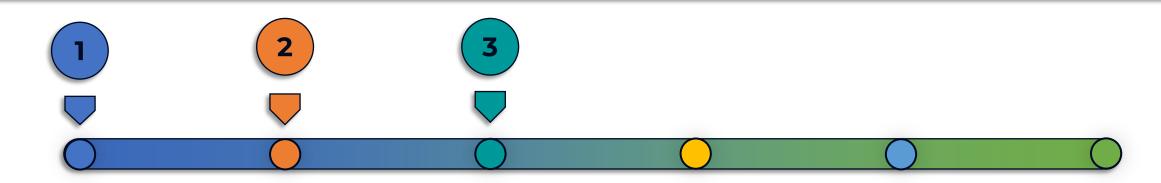
Process 03

Types of Submissions:

Template-based items

- An "actual item" to be used by the licensee.
- References approved template.
- Used to submit multiple items based on an approved template with changes to flavor or strain.

Template Items and Non-Templated-Based Items



STEP 1: New template item or non-templatebased item created in Metrc.



Metrc submission

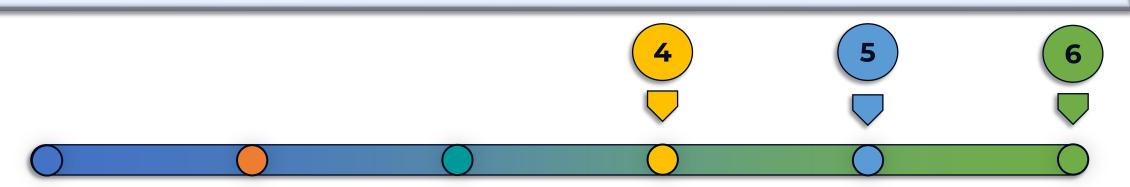
STEP 3: Complete submission?



DCR communicates by email with 30 days of the submission that the submission is incomplete DCR denies the item in Metrc.

Template Items and Non-Templated-Based Items

(Continued)



STEP 4:

The marijuana product, packaging and label design is reviewed by DCR for compliance with 19 CSR 100-1.120(1).



STEP 5: Compliant Submission



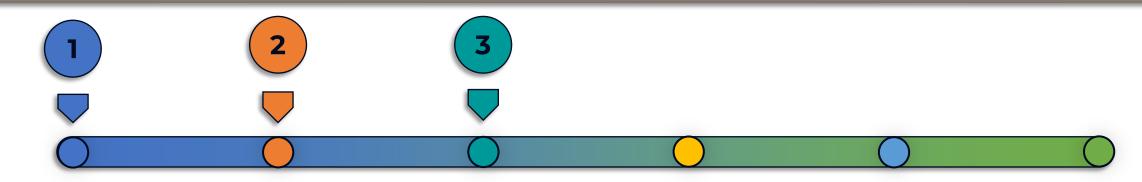
If "No"

The item is denied or rejected.
Licensee is sent notice of deficiencies.

STEP 6:

Item is approved in Metrc and receives an item approval number such as M0000###### immediately before the item name.

Template-Based Items



STEP 1: New template-based items created in Metrc.

A CSV of all associated items is emailed to cannabisproductcompliance@health.mo.gov with one (1) completed item approval application on the same day as the Metrc submission.

STEP 2:

STEP 3:

The template-based items are compared to the approved template item to verify the only differences are based on differing flavor or strain.

Template-Based Items (Continued)



STEP 4: Differences are only based on flavor or strain.



The item is denied or rejected. Licensee is sent notice of deficiencies.

STEP 5:

Item is approved in Metrc and receives an item approval number such as M00000######## immediately before the item name.

Template-Based Item Submission



- After a licensee has received DCR approval through the state-wide track and trace system (Metrc) for a new template item, the licensee may begin submitting items based on that approved template.
 - Items may only differ in flavor or strain. Certain areas of the approved-template are expected to change based on a different flavor or strain, and the licensee is required to demonstrate the areas that will differ through a placeholder on the template-item submission.
 - Licensees may submit all templated-based items associated with an approved template item at one time, which may allow for a reduced review time for each item.

Template-Based Item Submission (Continued)



- After a licensee enters all the approved template-based items for an approved template, the licensee should submit the data in a CSV (Microsoft Excel) file format to <u>CannabisProductCompliance@health.mo.gov</u>, along with a completed Item Approval Application.
- Licensees should submit the CSV file and Item Approval application with the following subject line: Licensee # Approved Template Number Item Name as shown below.
 - **Example:** MAN0000## M00000008101 TEMPLATE: DCR Labs Live Rosin Cart 1g –[Strain].
- Licensees are not required to submit unique labels when creating template-based items. Licensees may submit the same label file that was submitted with the original approved template with each subsequent template-based item. Additionally, licensees must attest that the template-based items will match the approved template item that is referenced on the application. If an approved template item has received approval for alternate placement of a label required by rule, the template-based item would automatically be approved for the same alternate placement.

Important Dates and Actions



September 1, 2024:

- All product produced at licensed facilities must be packaged in compliant packaging prior to transfer to a dispensary facility for sale to patients and consumers. Cultivation, manufacturing and dispensary licensees that package marijuana product for retail sale shall no longer use any packaging that is not in compliance with 19 CSR 100-1.120.
- Existing items at a cultivation or manufacturing facility or items that are packaged for retail sale by the dispensary licensee must be destroyed or repackaged into compliant packaging. DCR will discontinue any products in the state-wide track and trace system (Metrc) that have not been submitted and approved in accordance with 19 CSR 100-1.120 on August 31, 2024.

Other Actions

Important Dates and Actions



• November 1, 2024:

- Dispensary licensees may not sell any marijuana product that does not have an approved Item Approval number on the label required by 19 CSR 100-1.120(1)(C)2.L. Existing items at a dispensary facility must be either destroyed or repackaged into compliant packaging by the licensee that created the final marijuana product.
- Licensees should discontinue any marijuana product items in Metrc no longer produced by the licensee.
- Marijuana product transferred for retail sale to a dispensary licensee is required to be in a "final packaging" item category in Metrc. Licensees that are not using the "final packaging" item category to circumvent that preapproval process are in violation of **19 CSR 100-1** and subject to notices of violation, fines or other penalties.

Labeling - 19 CSR 100-1.120(1)(C)

- Labeling requirements apply to containers, wrappers, packages and methods of administration that contain marijuana product, unless specified.
 - "Marijuana" Clear and conspicuous including at least as large as any other words used. Required on all layers of packaging.

Example:

- Must be legible.
- At least as large as any other words used on that layer of packaging.
- On a single line of text.

Labeling - 19 CSR 100-1.120(1)(C)

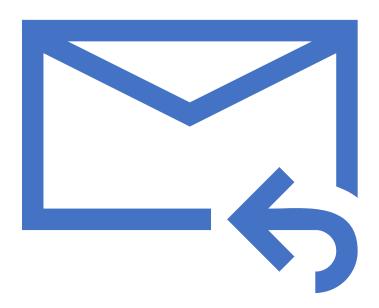
For more information visit:

https://health.mo.gov/safety/cannabis/facility-comms-guidance.php

product:

- Universal Symbol Clear, conspicuous and includes required elements.
 - Required on all layers of packaging.
 - Must measure one-half inch by one-half inch from point to point.
 - Infused edibles must be in compliance with 195.805 RSMo.
- "Compliance" Label
 - Display only information outlined by rule in the correct order, with the exception of variances.
 - Required on the marijuana product container closest to the product.

| · · | EST FOR ALTERNATIVE LABEL PLACEMENT (Section reserved for New Template and Non Template- items only) |
|---|---|
| <u>Instructions:</u> A licensee may request approval for alternative placement of "Marijuana", the universal symbol, and/or the label by completing this application section. | |
| For wh | nich labeling requirement(s) is the Licensee requesting alternative placement? (Check all that apply.) |
| "N | Aarijuana" |
| Universal Symbol | |
| Label required by Rule | |
| Provide detail about the alternative placement. Details must include: | |
| | Why the licensee cannot meet the rule requirement: |
| | |
| • | How the label placement will differ from rule: |
| | |
| • | How the proposed alternative label placement maintains and promotes safe use of the marijuana |



Contact and Important Information

Justin Smith

Compliance Assessment Unit Manager

Justin.smith@health.mo.gov

Arin Burnett

Product Compliance Team Supervisor

Arin.burnett@health.mo.gov

Email Inbox:

CannabisProductCompliance @health.mo.gov

DCR Facility Communication and Guidance Page:

https://health.mo.gov/safety/c annabis/facility-commsguidance.php

Item Approval Application:

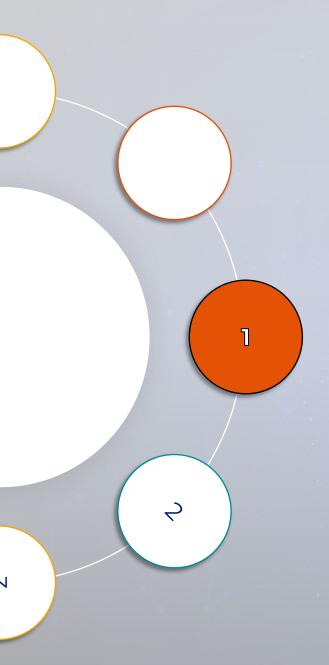
https://health.mo.gov/safety/cannabis/pdf/item-approval-application-052024.pdf



Testing and Research Unit

Focus Points

Sampling Expectations for 3 **Chain of Custody** Dispensary, Manufacturing, **Cultivation and Testing** Requirements Licensees **Expectations for Entering Results into the State-wide Reminders Track and Trace System**



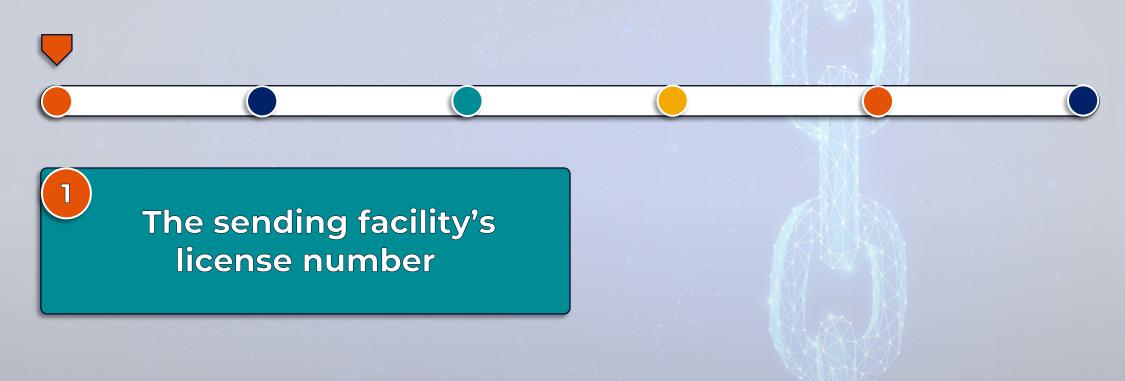
Focus Point 1

Chain of Custody Requirements

19 CSR 100-1.110(6)(E) Cultivation, manufacturing and dispensary licensees will collaborate with testing licensees to create a chain of custody record that includes at least the following information:

(Continued)

19 CSR 100-1.110(6)(E)



(Continued)

19 CSR 100-1.110(6)(E)



The sending facility's license number

 $(\mathbf{2})$

The legal name, address and contact information of the licensee sending the marijuana product for testing

(Continued) 19 CSR 100-1.110(6)(E)

1

The sending facility's license number

2

The legal name, address, and contact information of the licensee sending the marijuana product for testing

(3)

The testing facility's license number

(Continued)

19 CSR 100-1.110(6)(E)



The sending facility's license number

The legal name, address and contact information of the licensee sending the marijuana product for testing



The testing facility's license number



The legal name, address and contact information of the testing licensee

19 CSR 100-1.110(6)(E)

The sending facility's license number

The legal name, address, and contact information of the licensee sending the marijuana product for testing

3

The testing facility's license number

4

The legal name, address and contact information of the testing licensee

5

For each lot sampled -

(Continued)

19 CSR 100-1.110(6)(E)5

- A. The marijuana product category
- **B.** The marijuana product tag number
- C. Total mass of the harvest or process lot
- **D.** For infused products, the number of units for sale in the marijuana process lot
- **E.** The marijuana product sample tag
- **F.** The total mass of the marijuana harvest or process lot sample

- G. For infused products, the number of units sampled of the marijuana process lot
- H. Identification of the test or tests requested
- I. Whether the test or tests requested are for mandatory testing or for voluntary testing
- J. Whether a lot is being re-sampled because of a failed mandatory test
- K. Whether the marijuana product was remediated
- L. The date, name and signature of both the requesting facility's representative who was present for sampling and the testing facility's representative who conducted the sampling

Chain of Custody Record Retention Requirements

19 CSR 100-1.110(6)(F)

Chain of custody records must be retained by both the originating licensee and the testing licensee for at least five (5) years.



Focus Point 2

2

Expectations for Entering Results into the State-Wide Track and Trace System

19 CSR 100-1.110(7)(B)-(C) 19 CSR 100-1.110(9)(B)

Reporting Results

19 CSR 100-1.110(7)(B)

1. Within ten (10) days of collecting a sample and within twenty-four (24) hours of completing analysis of a sample, the testing licensee shall file a report in the state-wide track and trace system detailing at a minimum:

Δ.

All test results
showing
whether the lot
passed or failed
each required
test

В.

The certificate
of analysis
provided to the
licensee or third
party

C.

A photo of the sample received at the facility

Reporting Results (Continued)

19 CSR 100-1.110(7)(C)

Reporting of test results in the statewide track and trace system must coincide with or precede any notice of test results to the originating facility.

19 CSR 100-1.110(9)(B)

Voluntary testing may be completed on a schedule agreeable to the submitting facility, but all test results from voluntary testing must be reported in the state-wide track and trace system.



Focus Point 3

Sampling Expectations for Dispensary, Manufacturing, Cultivation and Testing Licensees

Order the correct test
batch and collaborate
with testing licensees to
verify accuracy of
information recorded on
the Chain of Custody

Ensure no more than one
(1) mandatory test is
completed on a lot unless
you receive written
approval by DCR

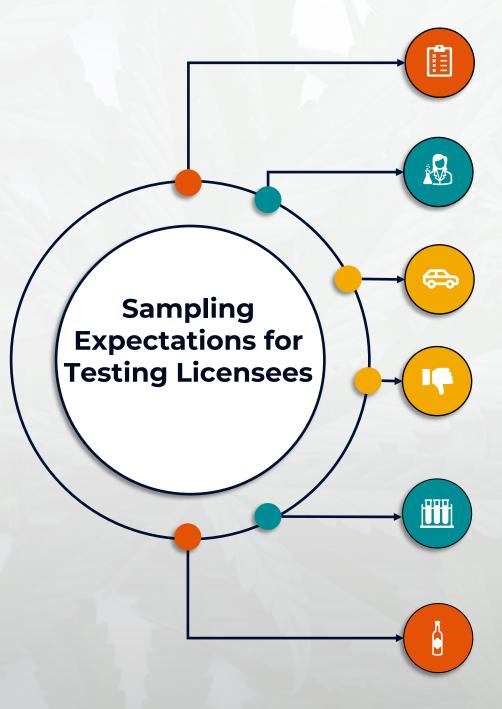
Ensure all processing of the lot is complete prior to sampling

Sampling
Expectations for
Dispensary,
Cultivation and
Manufacturing
Licensees

An employee of the originating license shall be present to observe the process and ensure a representative sample is taken

Ensure lot size meets rule requirement and ensure the entire harvest or process lot is available to the testing licensee for sampling

Have a designated sampling area that provides two (2) camera angles



Collaborate with originating licensees to verify accuracy of information recorded on the Chain of Custody

Physically and randomly sample product for mandatory testing without any interference, assistance or participation from the submitting licensee

Collect, store and transport samples in a way that mitigates contaminates

Testing Licensees shall **never** desiccate samples, pre-test samples, select the best or most desirable material from a lot or sample for testing, and/or manipulate samples

Ensure a representative sample is collected by following sampling requirements outlined in 19 CSR 100-1.110(5)(B)1.-3. and ensure that all harvest or process lots are adequately assessed for contaminants and that the cannabinoid profile is consistent throughout

Ensure marijuana product is either in its method of administration or **all** processing has been complete prior to sampling

Violations and Penalties

Violation of sampling requirements or manipulation of samples may result in fines up to one hundred thousand dollars (\$100,000) and suspension or revocation of license.





Weighing Out Samples

Testing licensees should be weighing out all nonunit-based samples.

Sample Retention Requirements

19 CSR 100-1.110(3)(D) Testing licensees shall retain all remaining sample for a minimum of thirty (30) days after testing is complete.

Consumer/Patient Cultivator Samples

Follow instructions for external incoming transfers.

Testing Facility Options

Ten (10) licensed testing facilities located throughout the state

https://health.mo.gov/safety /cannabis/licensedfacilities.php Contacting the Testing and Research Unit

testingandresearchunit@ health.mo.gov



Communication and Resources

Licensee Workshop

Tara McKinney
Public Outreach Director



DCR COMMUNICATION RESOURCES tay informed



Communication & Resource Center

One-stop shop



The Cannabis
Connection
Quarterly e-newsletter



DCR Podcast Monthly podcast



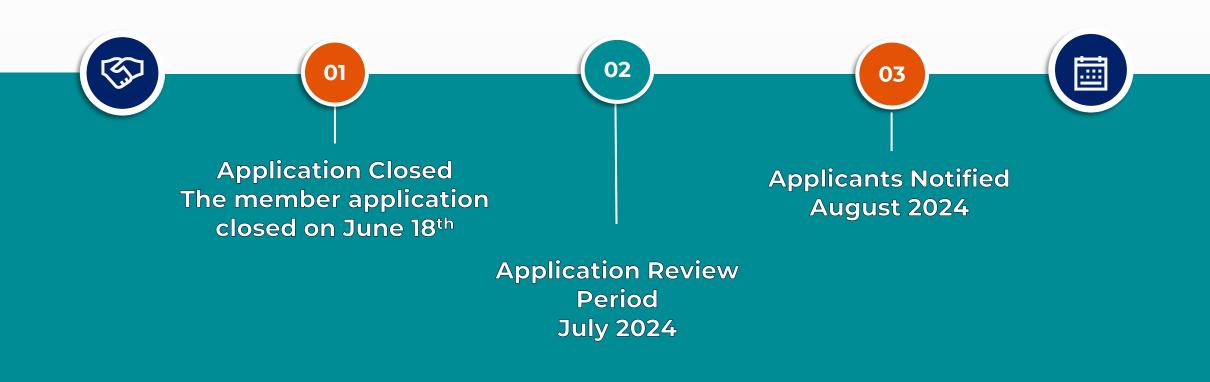
Email Subscription E-mail alerts



Cannabis.Mo.Gov

Missouri Cannabis Regulation Collaborative (MCRC)

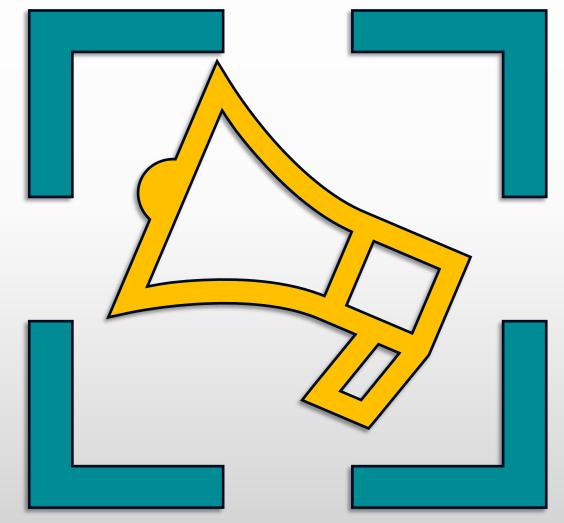
Timeline



Tell Us Something Good!

We love to hear from licensees. Is your business doing something innovative, interesting or new that you would like to share with us?

Email Tara McKinney, Public Outreach Director at **DCRC@health.mo.gov** and we may contact you for an in-person meeting with the DCR Director and Deputy Director to hear more about it!





Lesley Turek

Chief Equity Officer

Professional Background:

Lesley has been with the division since August 2023 as a Bureau of Business Licensing Services team supervisor. Previously Lesley was the director of Student Support Services and supervisor for Federal Programs within the Missouri Department of Elementary and Secondary Education. She was a middle school teacher for almost 15 years. Lesley received her B.A. in Communications, Minor in Journalism, Emphasis in Public Relations from Missouri Western State University, and a B.A.+ in Middle Childhood Education from Notre Dame College.



Tim Taylor

Project Specialist

Tim is working on a training for law enforcement that will provide information about the responsibilities of DCR as it relates to the rules and constitution.

Professional Background: Tim's career began in 1985 as a police officer and remained such for the next ten years where he worked in patrol, crime prevention and as a D.A.R.E. Officer. He spent 28 years in capacities including investigator, security coordinator and safety within the Secretary of State; Public Safety; and the last 23 years with MoDOT. He retired from MODOT on April 1, 2023.



Contact Us

Tara.McKinney@health.mo.gov

573-751-6257

Health.Mo.Gov



FINAL THOUGHTS

SCE Contact Information

Send any unanswered workshop questions to:

Business Licensing Services

CannabisLicense@health.mo.gov

Bureau of Facility Compliance

CannabisCompliance@health.mo.gov

Product Compliance Team

CannabisProductCompliance@health.mo.gov

Bureau of Investigation and Enforcement

CannabisComplaints@health.mo.gov

Testing and Research Unit

TestingandResearchUnit@health.mo.gov