

**Missouri Section for Medical Marijuana
Facility License & Compliance Section
Guidance Document 11
Material Deviation Guidance - Post Commencement**

Guidance Document 5 communicated the Department's guidance on material deviation applications for licensees who were not yet operational. The primary consideration in material deviation change requests for any facility that is not yet operational remains whether a change is one that impacts the facility's ability to fulfill key aspects of its proposed operations. However, and as noted in that guidance, the Department is now issuing guidance on the application of 19 CSR 30-95.040(4)(C)3 for facilities that have commenced.

For facilities that have commenced operations, the Department will likely consider to be material any change to a facility's physical design that 1) adds space to a structure or adds a new structure on the facility's premises, 2) alters the use of a space on the facility's premises, or 3) affects the physical security of the facility.

Examples of what changes might require a material deviation change request for operational facilities include:

- Expansions or additions to the facility's footprint or site plan that have not been approved already in an application for licensure or material deviation change request. These would be reviewed for whether the facility remains in compliance with requirements for distance from schools, churches, and daycares and with local government zoning requirements.
- Changes to room purposes, such as changing the location of a flowering plant room in a cultivation facility, an extraction room in a manufacturing facility, or a limited access area for a dispensary facility.
- Adding or removing fencing, cameras, secure or unsecure access points, drive-through windows, or alarm systems/mechanisms, or making other changes to the physical security of the facility.

Of course, for location changes per 19 CSR 30-95.040(4)(C)3.D, we will also review for whether operating the facility at its original location is unduly burdensome for the licensee and whether claims made in the facility's initial licensure application regarding benefits of its original location also apply to the facility's newly proposed location.

If a physical design change does not implicate any of the above, it is unlikely an application for change will be necessary. For instance, additions of a vehicle, changes in operations, or changes in contracts/agreements would not likely require a material deviation change request. As always, if you have any questions about whether a particular change you are making would require a material deviation application, you may reach out to your license specialist for guidance specific to your circumstances.

While most material deviation applications for operational facilities will no longer focus on the licensee's initial application, please keep in mind that the licensee's initial proposal, as modified through change requests, will always remain important for renewal of the license. Per 19 CSR 30-95.040(1)(F)1, "If a facility provides false or misleading information in an application, its application may be denied or, if the

information is later discovered to have been false or misleading, its license or certification may be revoked. Plans, assurances, and projections offered in answers to 19 CSR 30-95.025(4) evaluation criteria questions may be considered false or misleading if, upon application for license renewal, the department determines the facility has not made a reasonable effort to implement or follow-through on those plans, assurances, or projections.” It is important to note that this is an obligation applicable to the license. Changes in leadership or ownership, even after a transfer of license to a new entity, would not change the obligation of the licensee at time of license renewal. Any changes related to operations that were proposed in a licensee’s application or approved via a change request, such as adding or suspending services or changing product lines or processes, should be communicated to the facility’s Compliance Officer for appropriate action. Communicating changes as they happen or before is one of the best ways a licensee can ensure it is prepared for its renewal period.

A final note: This guidance only relates to what may require a material deviation change request for operational facilities. It does not affect what would be required for facilities that are still working toward a Commencement Inspection and does not change the expectation that certain new facility spaces, such as vehicles or additional phases of construction, must be inspected before they may be used.