Colorado Department of Revenue MED

Science & Policy Work Group Meeting

MED Rulemaking Meeting Friday, January 8, 2021

MED Winter Rulemaking Schedule

Rule Comment Form



Winter Rulemaking Proposals

- 1. Definitions
 - Decontamination
 - Remediation
- 2. Decontamination
 - Allow Additional Decontamination Attempts for Harvest Batches that Failed Microbial Contaminant Testing.
- 3. Centralization of Cultivation Operations



Definitions

Current Regs:

- <u>Decontamination</u> Not defined in current regs.
- Remediation "Remediation means the process by which Regulated Marijuana flower and trim, which has failed microbial testing, is processed into a Solvent-Based Medical Marijuana Concentrate, or into Solvent-Based Retail Marijuana Concentrate and retested as required by these rules."

Proposal: (*Includes moving current definition of Remediation to failed testing rules)

- <u>Decontamination:</u> the process of neutralization or removal of dangerous substances or other contaminants from regulated marijuana <u>without</u> changing the form of the regulated marijuana.
- <u>Remediation:</u> the process of neutralization or removal of dangerous substances or other contaminants from regulated marijuana <u>while</u> changing the form of the regulated marijuana.



Additional Decontamination Attempts

Proposal:

- Limited the additional decontamination attempts to flower, wet whole plant, or trim that fails microbial contaminant testing.
- Requires mycotoxin testing after a package or Harvest Batch fails two microbial contaminant tests.
- The mycotoxin testing can occur after the package or Harvest Batch has passed microbial contaminant testing.

MED and CDPHE Considerations:

- Regardless of the number of fails, once the package or Harvest Batch passes microbial contaminant testing subsequent to a fail, mycotoxin, water activity, and potency testing must be conducted.
- Language that licensees must maintain SOPs detailing decontamination method they implement.
- Language that licensees must collect and maintain data documenting the effectiveness of the decontamination method to address the failed microbial contaminant test.



Centralization of Cultivation Operations

Proposal: Expand the current allowance for the Transfer of Harvest Batches to another cultivation facility for the purposes of decontamination to include additional cultivation operation procedures, such as curing and trimming.

Requires:

- The cultivation facility receiving the transfer is identified in the inventory management system;
- Inventory is weighed prior to leaving and upon receipt at the receiving cultivation facility;
- The transfer is completed on the same business day and all required weights are measured on the same business day;
- The receiving cultivation facility is responsible for compliance with all testing requirements (regardless of any testing performed prior to transfer);
- Standard operating procedures for each cultivation facility clearly reflect the steps taken by each facility; and
- The receiving cultivation facility test at least the first five transfers received from any licensee for all contaminant tests.



Centralization of Cultivation Operations cont.

MED and CDPHE Considerations:

- Requiring the cultivation facilities to have an established ownership connection (identical or common ownership).
- Limiting an originating cultivation facility to using only one centralized cultivation facility in a 12 month period.
- Rather than requiring the process to be completed on the same business day, consider a 12 hour window from initiation of transfer.
- Require that SOPs detail the specific conditions of transfer and transport to include type and weight of packaging, specifics of shipping containers to be used, etc.
- If the receiving cultivation facility is seeking process validation, process validation must be obtained separately for marijuana received from each originating facility.
- Language that the receiving cultivation facility must maintain and produce complete testing records that can verify that facility's compliance with testing and process validation requirements.

