

Compliance Tip June 2, 2023

Topic: Third-Party Decontamination Guidance

Applicable Rules: 1-115, 4-110, 4-135, 5-205, 6-205, 6-705

The Colorado Department of Revenue's Marijuana Enforcement Division (MED) is issuing this Compliance Tip to highlight certain regulations, offer information, and provide guidance to Licensees regarding the use of a third-party Regulated Marijuana Business for Decontamination of Regulated Marijuana after it has failed contaminant testing or prior to testing.

Decontamination and Remediation (Rule 1-115)

- *Decontamination* is a process that removes or neutralizes dangerous substances from the marijuana without changing the actual product type or category of the marijuana. For example, after a Harvest Batch of marijuana flower has been decontaminated (after the Decontamination process is complete), the marijuana remains in the form of flower rather than having been changed into a different marijuana category (such as a Regulated Marijuana Concentrate or Marijuana Product).
- Remediation is a process that removes or neutralizes dangerous substances from the marijuana and results in changing the product type or category of the marijuana. For example, after a Harvest Batch of marijuana flower has been remediated (after the Remediation process is complete), the marijuana has been transformed into a different marijuana category. Remediation is allowed in only two scenarios: (1) Marijuana flower that failed for microbial contamination may be processed into solvent-based Regulated Marijuana Concentrate and (2) marijuana flower that has failed for elemental impurities may be processed into Regulated Marijuana Concentrate. [Refer to Colorado Marijuana Rule 4-135 (C)(3)(b), (C.5)(3)(b), and (D.1)(3).]

Contaminant Testing and Decontamination

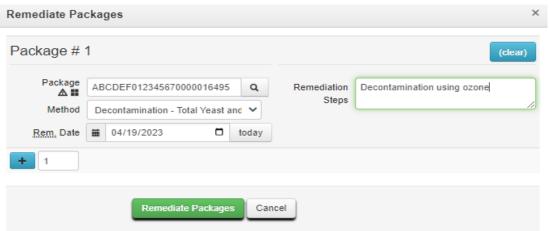
 Per Marijuana testing rules (Part 4—Regulated Marijuana Testing Program), all Regulated Marijuana and Marijuana Product (referred to here as "marijuana") must pass contaminant testing at a Regulated Marijuana Testing Facility before Transfer or manufacturing, unless the origin cultivating or manufacturing business has achieved Reduced Testing Allowance status, or a specific exemption is detailed in Marijuana Rules (e.g., third-party decontamination or use of a centralized processing hub). Licensees are permitted to conduct Decontamination prior to the submission of Test Batches to Regulated Marijuana Testing Facilities and to incorporate these measures into their cultivation and/or manufacturing process. These Decontamination procedures and measures must be detailed in the Regulated Marijuana Business's standard operating procedures (SOPs).

• If a Test Batch fails contaminant testing, the Regulated Marijuana Business (referred to here as "business") may choose to decontaminate the package (commonly referred to as a "mother package"), Harvest Batch, or Production Batch from which the failed contaminant Test Batch originated (or the business may choose to destroy it).

The business may also send flower-based marijuana that failed contaminant testing to a Medical or Retail Marijuana Products Manufacturer business to be processed into a Solvent-Based Regulated Marijuana Concentrate through a Remediation process.

Contaminant testing must be performed prior to a Cultivation transferring to a Manufacturer, even for Decontamination purposes.

- If the Test Batch from a package, Production Batch, or Harvest Batch fails contaminant testing and the business does not have the ability to decontaminate the marijuana, that business may choose to Transfer the package or batches (harvest/production) to another business for Decontamination. The business performing the Decontamination would be considered the "third party."
- Decontamination/Remediation following failed contaminant testing must be entered into the State Inventory Tracking System (Metrc) and Decontamination/Remediation types must also be entered. Information regarding documenting Decontamination/Remediation in Metrc may be found in Metrc Industry Bulletin 5.5.21 (Centralized Processing Hub and Decontamination).



MED identifies Decontamination and Remediation as two distinct processes; however, when entering Decontamination measures into Metrc, the Remediation button must be used. MED is actively working with Metrc on separating the Decontamination and Remediation functionality pathways.

- Prior to transfer to a third party for Decontamination, the cultivation must package the entire Harvest Batch (attaching and assigning an RFID tag) and transfer that package or packages to the Decontamination facility. After that package is transferred to and subsequently returned from the Decontamination facility, the origin cultivating business must create a Test Batch directly from that package or packages (rather than from the original Harvest Batch) and document this accurately in Metrc. Test results will apply *only* to Packages that were included in the Test Batch. In other words, test results will not be applied to Packages that were not included in the Test Batch and will not apply to the upstream Harvest Batches. This process should be followed even when this Harvest Batch is being used in achieving Reduced Testing Allowance.
- Except for Pesticide and Elemental Impurities testing, if the Harvest Batch was tested and failed prior to Decontamination, Marijuana Rules for retesting apply: two separate Test Batches must be created and submitted either to the original Marijuana Testing Facility where the tests failed previously or to two different Marijuana Testing Facilities. Refer to the section below regarding the relevant rules.

For failed Pesticide or Elemental Impurities tests, Decontamination is *not* permitted. Retesting may be performed by contacting the Testing Facility and requesting that retests be performed on the original Test Batch.

Rules Relevant to Third-Party Decontamination

Licensees are encouraged to review Marijuana Rule 4-135 (Regulated Marijuana Testing Program: Contaminated Product and Failed Test Results and Procedures), Rule 4-120 (Regulated Marijuana Testing Program: Contaminant Testing), Rule 4-121 (Regulated Marijuana Testing Program: Wet Whole Plant Contaminant Testing), and Rule 4-110 (Regulated Marijuana Testing Program: Sampling Procedures).

Different Decontamination, Remediation, and retesting options are available depending on the applicable section of Marijuana Rule 4-135. Restrictions and options applicable to each of these sections are listed below.

Rule 4-135(C)(3). Failed Contaminant Testing: Microbial Testing of Regulated Marijuana Flower, Wet Whole Plant, Trim, Pre-Rolled Marijuana, and Infused Pre-Roll Marijuana.

• Third-party Decontamination may occur at cultivating or manufacturing businesses. However, Remediation may occur only at a manufacturing business.

- Decontamination may be performed as many times as needed.
- If marijuana is sent back to the cultivating/manufacturing business before distribution, the cultivating/manufacturing business is responsible for testing.
- If marijuana will be distributed by the business that performed the Decontamination, the business performing the Decontamination is responsible for testing.
- Microbial, mycotoxin, and water activity tests must be performed after Decontamination or Remediation has been completed.

Rule 4-135(C.5). Failed Contaminant Testing: Water Activity Testing (Wet Whole Plant exempt).

- Third-party Decontamination may occur at cultivating or manufacturing business. However, Remediation may occur only at a manufacturing business.
- Decontamination may be repeated as many times as needed.
- If marijuana is sent back to the cultivating/manufacturing business before distribution, the cultivating/manufacturing business is responsible for testing.
- If marijuana will be distributed by the business that performed the Decontamination, the business performing the Decontamination is responsible for testing.
- A water activity retest must be performed after Decontamination, along with a microbial test. Note that if the microbial test fails, Licensees must follow Rule 4-135(C).
- Microbial, mycotoxin, and water activity tests must be performed after Remediation.

Rule 4-135(B)(3). Failed Contaminant Testing: All Contaminant Testing except Microbial and Water Activity Testing of Regulated Marijuana Flower, Trim, Pre-Rolled Marijuana, Infused Pre-roll Marijuana, Pesticide Testing, and Elemental Impurities Testing of Regulated Marijuana Flower or Trim.

- Decontamination may be performed only once.
- Third-party Decontamination may occur only at a manufacturing business.
- If one or both retests fail, destruction of the corresponding package or batch (Harvest Batch or Production Batch) must be performed.
- The decontaminated marijuana must undergo the same test type that it previously failed.
- Marijuana Rules do not specify whether the cultivating/manufacturing business or the third party pays testing costs.

Adulteration or Alteration of Test Batches Prohibition

All Test Batches submitted for any testing must be representative of the batch (Harvest Batch or Production Batch) or of the Regulated Marijuana Product from which the Test Batch was collected. *Test Batches must not be treated separately or isolated in any way.* Test Batches must

be collected after all processing steps are completed as detailed in a business's SOPs. MED encourages the review of Marijuana Rule 4-110(A)(3).

Transferring to a Third Party for Decontamination

- Metrc contains transfer types specific to Decontamination. When transferring to and from a third-party Decontamination business, these transfer types should be used:
 - Affiliated (Decontamination). This transfer type denotes transfers to another licensed facility where the marijuana will be decontaminated and the owners are:
 - the same individuals or entities.
 - individuals who are related by blood or marriage, or
 - entities that are directly or indirectly under common control.
 - *Unaffiliated (Decontamination)*. This transfer type denotes transfers to another licensed facility where the marijuana will be decontaminated and the owners do not meet the criteria above (thus is not associated with the origin business).

For any questions surrounding transfer types and when each type is to be used, please visit the <u>Division of Taxation's marijuana website</u>.

- A Centralized Distribution Permit is not required to conduct third-party Decontamination. (Refer to Rule 5-205—Medical Marijuana Cultivation Facility: License Privileges. H. Centralized Distribution Permit, and Rule 6-205—Retail Marijuana Cultivation Facility: License Privileges. I. Centralized Distribution Permit.)
- Additionally, centralized processing hubs are not required to conduct third-party
 Decontamination. (Refer to Rule 5-205—Medical Marijuana Cultivation Facility: License
 Privileges. H. Centralized Distribution Permit, and Rule 6-205—Retail Marijuana Cultivation
 Facility: License Privileges. I. Centralized Distribution Permit.)

Third-Party Decontamination Facilities

- Cultivations performing third-party Decontamination must comply with Rules 5-225(C)/6-220(C), which pertain to Inventory Management. Marijuana that will be decontaminated or that has already been decontaminated is categorized as on-hand inventory until it is transferred out of the Cultivation.
- Facilities performing third-party Decontamination should use the Affiliated (Decontamination)/Unaffiliated (Decontamination) transfer types in Metrc to document transfers back to the origin business.

Best Practices

- Businesses that choose to incorporate third-party Decontamination into their standard business procedures must detail these procedures in their SOPs [Rule 3-905(B)], and the two businesses will determine the agreed-upon details of the Decontamination process.
- Marijuana Rules do not specify whether the cultivating/manufacturing business or the third party is responsible for testing:
 - MED encourages third-party Decontamination procedures similar to those pertaining to failed contaminant testing.
 - The third-party business that performed the Decontamination may submit Test Batches for R&D testing; however, R&D testing may not serve as a substitute for required testing of the decontaminated product.

Helpful Links

- <u>Industry Bulletin 21-06</u>: Implementation of New Testing and Decontamination Rules.
- <u>Metrc Industry Bulletin 5.5.21:</u> Centralized Processing Hub and Decontamination / Remediation.
- MED Compliance Tip, 11.1.22: Inventory Management of Regulated Marijuana.