

**DEPARTMENT OF REVENUE
Marijuana Enforcement Division
COLORADO MARIJUANA RULES
1 CCR 212-3**

Part 4 – Regulated Marijuana Testing Program

Basis and Purpose – 4-136

The statutory authority for this rule includes but is not limited to sections 44-10-202(1)(c), 44-10-202(1)(e), 44-10-202(4), 44-10-203(1)(j), 44-10-203(2)(d)(I)-(III), (VI), C.R.S. The purpose of this rule is to establish limited conditions under which Licensees may Transfer Regulated Marijuana contaminated by metals as part of a metals remediation project. A metals remediation project initiated pursuant to this rule is intended to generate data for the Licensee and the Marijuana Enforcement Division, in consultation with the Colorado Department of Public Health and Environment, to further assess, research, analyze, or evaluate the safety and viability of Remediation of Regulated Marijuana contaminated by metals. Pursuant to only this rule, Licensees may, after submission and approval of a project proposal, Transfer Harvest Batches with metals contamination for processing into Regulated Marijuana Concentrate. Any Regulated Marijuana Transferred pursuant to this rule, including Regulated Marijuana Concentrate produced from Regulated Marijuana with metals contamination, cannot be Transferred for consumption and must be destroyed and disposed of according to the requirements of this rule. The state licensing authority adopted this rule after finding insufficient evidence and other data available to determine or otherwise assess the safety or viability of Remediation for Regulated Marijuana subject to metals contamination.

4-136 – Metals Remediation Project for Harvest Batches with Metals Contamination

A. Authorized Transfers of Regulated Marijuana Pursuant to a Metals Remediation Project. A Medical Marijuana Cultivation Facility or a Retail Marijuana Cultivation Facility that possesses Harvest Batches of Regulated Marijuana that failed required metals contaminant testing may Transfer any such Harvest Batch of Medical Marijuana to a Medical Marijuana Products Manufacturer, and may Transfer any such Harvest Batch of Retail Marijuana to a Retail Marijuana Products Manufacturer, for the sole purpose of allowing the Regulated Marijuana to be used in an approved metals remediation project regarding the safety and efficacy of removing metals contamination from Regulated Marijuana. All Transfers authorized by this Rule 4-136 are subject to the following requirements and restrictions:

1. Metals Remediation Project Proposal. Prior to any Transfer of a Harvest Batch of Regulated Marijuana pursuant to this rule, the Regulated Marijuana Businesses must submit a proposal to, and receive approval from, the Division to engage in a metals remediation project. A Regulated Marijuana Business that has received Division approval of its proposal to engage in a metals remediation project may Transfer, process, and test Regulated Marijuana in a manner consistent with the approved proposal and subject to the requirements and restrictions of this Rule 4-136. A Regulated Marijuana Business's metals remediation project proposal must, at a minimum, provide the following:
 - a. Licensee Information. The proposal must provide the names of all Regulated Marijuana Businesses that will be participating in the metals remediation project, including the legal business name(s) and license number(s):
 - b. Description of Experiments. The proposal must provide a description of the experiments and any related research the Regulated Marijuana Business intends to conduct or otherwise engage in as part of the metals remediation project. The description must provide details regarding the Regulated Marijuana Business's

intended processing methods, testing plans that include a summary of tests that will be performed, and the objectives of experiments and any related research. Any experimentation and related activities associated with an approved metals remediation project proposal shall not involve human subjects or otherwise permit the consumption of any Regulated Marijuana that will be Transferred or otherwise used as part of a metals remediation project.

- c. Target Dates. The proposal must provide the target dates for the initiation and completion of experiments and any related research the Regulated Marijuana Business will engage in as part of the metals remediation project;
- d. Quantity or Amounts of Regulated Marijuana. The proposal must provide the estimated amount of Regulated Marijuana the Regulated Marijuana Business intends to Transfer, and the estimated amount of Regulated Marijuana Concentrate the Regulated Marijuana Business expects to yield, as part of the metals remediation project;
- e. Health and Safety Procedures and Protocols. The proposal must provide the Regulated Marijuana Business's safety procedures and any protocols intended to protect the health and safety of all parties involved in activities associated with the metals remediation project and any other Person who may come into contact with metals contaminated Regulated Marijuana and the resulting Regulated Marijuana Concentrate;
- f. Waste Management and Disposal Plans. The proposal must include the Regulated Marijuana Business's waste management and disposal plans for Regulated Marijuana that will be used for the metals remediation project. When providing this information, the Regulated Marijuana Business must:
 - i. Consider any applicable hazardous waste requirements and ensure disposal plans describe any measures that are intended to prevent environmental harms and any related risks; and
 - ii. Describe plans for managing and disposing of any metals-contaminated plant material, byproduct, and/or metals residue expected to be generated or remain from the Regulated Marijuana Business's remediation efforts associated with the project.
- g. Acknowledgement of Information-Sharing Requirements. The proposal must include a statement representing the Regulated Marijuana Business's agreement to share data and information generated from experiments and any related research conducted pursuant to this rule, which will include a report of experimental findings, raw data, and the results of all testing performed for any Harvest Batch or Production Batch of Regulated Marijuana used for the metals remediation project;
- h. Acknowledgement of Destruction and Disposal Requirements. The proposal must include a statement representing the Regulated Marijuana Business's agreement to ensure the destruction and disposal of all Regulated Marijuana Transferred or otherwise used for the metals remediation project, including the destruction and disposal of any Production Batches of Regulated Marijuana Concentrate produced as part of the project, regardless of the test results; and
- i. Authorization from Controlling Beneficial Owners. The proposal must include a statement representing that all Controlling Beneficial Owners of the Regulated

Marijuana Business authorize submission of the proposal on behalf of the Regulated Marijuana Business.

2. Transfer and Storage Restrictions.

- i. Licensees are prohibited from Transferring any Regulated Marijuana subject to a metals remediation project to any Medical Marijuana Store, Retail Marijuana Store, patient, consumer, or in any other manner that allows the Regulated Marijuana to be consumed. The restrictions established under this subparagraph (2) apply regardless of whether the Regulated Marijuana received passing test results from any tests conducted as part of the project.
- ii. Regulated Marijuana Transferred pursuant to this Rule 4-136 must be stored in a manner intended to prevent cross-contamination or co-mingling with any Regulated Marijuana inventory intended for Transfer to patients or consumers.

3. Data and Information Related to an Approved Metals Remediation Project. A Regulated Marijuana Business engaging in conduct pursuant to an approved metals remediation project must provide the Marijuana Enforcement Division with all data and information generated from experiments and any related research conducted pursuant to this rule, which shall at a minimum include a report of experimental findings, raw data, and the results of all testing performed for any Harvest Batch or Production Batch of Regulated Marijuana used as part of the metals remediation project.

- i. A Regulated Marijuana Business engaging in conduct pursuant to an approved metals remediation project must maintain copies of all data and materials prepared for and generated from an approved metals remediation project in accordance with Rule 3-905.
- ii. The data and information provided to the Marijuana Enforcement Division and maintained pursuant to this rule shall be subject to inspection by the Colorado Department of Public Health and Environment.
- iii. A Licensee's engagement in an approved metals remediation project does not mean the data and information generated from the project will be sufficient for the State Licensing Authority to reach any conclusions regarding the safety and viability of Remediation of metals contaminated Regulated Marijuana.

4. Destruction and Disposal Requirements. All Regulated Marijuana Transferred or otherwise used as part of a metals remediation project under this rule must be destroyed and disposed of at the conclusion of an approved metals remediation project or as otherwise directed under these rules. The destruction and disposal requirements established under this paragraph (4) apply to all Regulated Marijuana Transferred or otherwise used for the metals remediation project, including Regulated Marijuana Concentrate produced from metals contaminated Harvest Batches, and regardless of test results associated with the project.

5. Timeline for Activities Authorized Under an Approved Metals Remediation Project. All Transfers and any other activities associated with an approved metals remediation project or otherwise authorized by this Rule 4-136 shall conclude within 120 days from the adoption of this Rule 4-136 or upon its repeal. A Licensee's engagement in an approved metals remediation project does not impose any deadline by which the State Licensing Authority may reach a conclusion regarding the safety or viability of Remediation of metals contaminated Regulated Marijuana.

6. Violation Affecting Public Safety. Any violation of this Rule may be a violation affecting public safety. See Rule 8-235 Penalties.