



**COLORADO DEPARTMENT OF REVENUE
MARIJUANA ENFORCEMENT DIVISION**

Emergency Rule Adoption

New Rule, 1 CCR 212-3

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

Statement of Emergency Justification and Adoption

Pursuant to sections 24-4-103 and 44-10-203, C.R.S., I, Heidi Humphreys, Deputy Executive Director of the Department of Revenue and State Licensing Authority, hereby adopt the aforementioned Colorado Marijuana Rule attached hereto.

Section 24-4-103(6), C.R.S., authorizes the State Licensing Authority to issue an emergency rule if the State Licensing Authority finds that the immediate adoption of the rule is imperatively necessary to comply with state law, or for the preservation of public health, safety, or welfare, and compliance with the requirements of section 24-4-103, C.R.S., would be contrary to the public interest. I find: (1) the immediate adoption of this new rule is necessary to comply with the constitutional and statutory mandates of the Colorado Marijuana Code, sections 44-10-101 *et seq.*, C.R.S.; (2) the immediate adoption of this new rule is necessary to preserve the public health, safety, and welfare; and (3) compliance with the notice and public hearing requirements of section 24-4-103, C.R.S., would be contrary to the public interest.

Statutory Authority

The statutory authority for the attached rule is identified in the statement of basis and purpose preceding the rule. Statutory authority for this rule includes but is not limited to section 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.

Purpose for Emergency Rule

The purpose of this new rule on an emergency basis is to establish limited conditions under which Licensees may Transfer¹ Regulated Marijuana contaminated by metals as part of a metals remediation project specifically intended to generate data necessary to further assess, research, analyze, or evaluate the safety and viability of remediation of Regulated Marijuana contaminated by metals.

The Colorado Marijuana Code, Section 44-10-202 *et seq.* requires the State Licensing Authority to establish a testing and certification program for Regulated Marijuana. Statute directs that such program require testing to ensure Regulated Marijuana sold for human consumption does not contain contaminants that are injurious to health and to ensure correct labeling. See 44-10-203(2)(d)(I), C.R.S. The state's Regulated Marijuana testing program, which establishes minimum required testing standards, is reflected in Part 4 of the [Colorado Marijuana Rules, 1 CCR 212-3](#).²

¹ "Transfer" means to grant, convey, hand over, assign, sell, exchange, donate, or barter, in any manner or by any means, with or without consideration, any Regulated Marijuana from one Licensee to another Licensee, to a patient, or to a consumer. See Rule 1-105, 1 CCR 212-3.

² As part of the Division's [2020 Rulemaking Session](#), the State Licensing Authority adopted new and amended rules, effective January 1, 2021. See the [Colorado Marijuana Rules, 1 CCR 212-3, effective Jan. 1, 2021](#).

Further, on January 1, 2020, Regulated Marijuana became subject to required metals contaminant testing.³ Leading up to this effective date and to support compliance with new rules, the Marijuana Enforcement Division notified Licensees of metals testing requirements on [January 23, 2019](#), [June 21, 2019](#), and [December 30, 2019](#).

Under current rules, if a Medical Marijuana Cultivation Facility or Retail Marijuana Cultivation Facility possesses Regulated Marijuana that fails required **microbial** contaminant testing, the Licensee may Transfer such Regulated Marijuana to a Medical or Retail Marijuana Products Manufacturer for purposes of Remediation (allowing the Regulated Marijuana to be processed into a solvent-based concentrate).⁴ However, such allowances for Transfer and Remediation do not extend to Regulated Marijuana that fails any other categories of required testing. Therefore, Regulated Marijuana that fails required metals contaminant testing cannot be Transferred for any purpose, including for purposes of Remediation. As a result, Regulated Marijuana that fails metals contaminant testing must be destroyed.

On or about October 20, 2020, the Marijuana Enforcement Division identified an increase in reported numbers of failed metals testing results for Regulated Marijuana from Licensees operating outdoor cultivations. The Marijuana Enforcement Division has also since received numerous requests to consider allowances for Remediation of Regulated Marijuana that failed required metals contaminant testing. Absent such an allowance, a Regulated Marijuana Business may be required to destroy large quantities of inventory due to failed metals testing results. Further, Licensees have informed the Marijuana Enforcement Division that they believe it is possible to safely Remediate Regulated Marijuana with metals contamination in a manner that renders the inventory safe for human consumption.

The State Licensing Authority finds there is insufficient evidence and other data available to determine or otherwise evaluate the safety or viability of Remediation for Regulated Marijuana subject to metals contamination. Therefore, and based on the following additional considerations and expectations, the State Licensing Authority adopts the attached Emergency Rule to establish limited conditions under which a Licensee may engage in an approved metals remediation project:

- a) The potential for large quantities of inventory that may be subject to destruction requirements under current rules due to failed metals testing and related impacts on individual businesses and on overall market supply;
- b) Licensee assertions that Regulated Marijuana subject to metals contamination can be Remediated in a manner that can render the Regulated Marijuana safe for human consumption;
- c) The Marijuana Enforcement Division's assertion that it cannot claim that Remediation of Regulated Marijuana subject to metals contamination is either safe or unsafe for human consumption, but that limited-scope allowances for Transfer and testing consistent with the attached Emergency Rule can generate data critical to informing the safety and viability of this option;
- d) The Colorado General Assembly's direction [reflected in the Colorado Marijuana Code, Section 44-10-203(2)(d)(I), C.R.S.], to establish a testing program to ensure Regulated Marijuana sold for human consumption does not contain contaminants that are injurious to health and to ensure correct labeling;
- e) The data and information related to the metals remediation project and generated pursuant to the attached Emergency Rule will be provided and used to inform further initiatives by the Marijuana Enforcement Division, in consultation with the Colorado Department of Public Health and Environment, to further assess, research, analyze, or

³ Pursuant to Rule 4-120(C)(5), 1 CCR 212-3, required metals contaminant testing is intended to determine the presence and amounts of arsenic, cadmium, lead, and mercury. Other categories of required tests include residual solvent, microbial, mycotoxin, pesticide, and potency testing.

⁴ Regulated Marijuana subject to Remediation See Rule 4-135(C), 1 CCR 212-3.

- evaluate the safety and viability of Remediation methods for Regulated Marijuana with metals contamination; and
- f) Any Regulated Marijuana subject to Transfers, processing, research, and other activities authorized by the Emergency Rule cannot be Transferred to any person for consumption.

Effective Date of Emergency Rules and Permanent Rulemaking

The attached Emergency Rule is effective immediately upon adoption.

Unless otherwise noted in the Emergency Rule provision, the attached Emergency Rule remains in effect pursuant to section 24-4-103(6), C.R.S., of the state Administrative Procedure Act, for 120 days from the date of adoption, or until repealed by the State Licensing Authority upon filing of a notice of such with the Secretary of State.

Heidi Humphreys

Digitally signed by Heidi Humphreys
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12/17/2020

Heidi Humphreys
Deputy Executive Director/Chief Operating Officer
Colorado Department of Revenue
State Licensing Authority

Date

**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.