



## Compliance Tip

August 24, 2021

**Topic: Achieving and Maintaining Process Validation for Contaminants**

**Applicable Statutory Sections and/or Rules: [1 CCR 212-3](#) Rule 4-120**

The Colorado Department of Revenue's Marijuana Enforcement Division (MED) is issuing this Compliance Tip to highlight regulations related to achieving and maintaining process validation for contaminant testing. The information contained herein is for informational purposes only and should not be construed as legal advice on any subject matter.

### **General Guidance**

#### **Process Validation Explained:**

Process validation refers to the collection and evaluation of test samples, which represent the final product of the Harvest or Production Batch. Process validation is an optional process; however, achieving process validation can create business efficiencies by decreasing the frequency at which Harvest or Production Batches must be tested.

#### **Achieving Process Validation:**

A Regulated Marijuana Business that is a cultivation or products manufacturer can achieve process validation for contaminant testing by following the testing requirements in [Rule 4-120](#).

#### **Required Contaminant Tests:\***

- Microbials
- Heavy Metals
- Pesticides
- Residual Solvents

Potency testing is a separate required test and does not fall under contaminant testing.

*\* Mycotoxin testing is not eligible for achieving process validation.*

**In order to achieve process validation for a specific contaminant test type, all tests for that contaminant test type must pass testing. If a Harvest or Production Batch fails a test for a contaminant test type when attempting to achieve process validation, the business must restart all steps for achieving process validation. Even if two subsequent retests of a Harvest or Production Batch pass, the initial failed test for the Harvest or Production Batch requires the business to restart all steps for achieving process validation. For the purposes of process validation, a batch that has failed the initial contaminant test is considered failing, irrespective of passing retests.**

A Regulated Marijuana Business that is a cultivation or products manufacturer can achieve process validation for required contaminant testing at the same time or separately for each required contaminant test. Process validation is valid for one year from the date of the creation of the first Harvest or Production Batch that passed process validation testing.

To achieve process validation, a Regulated Marijuana Business must have written Standard Operating Procedures (SOPs) that clearly describe all steps and parameters of cultivating, harvesting, drying, curing, trimming, manufacturing, packaging, storing, and sampling for testing Regulated Marijuana or Regulated Marijuana Products. Employees must be adequately trained on these SOPs. Please reference [Rule 5-315 \(B\)\(7\) and 6-315 \(B\)\(7\)](#) for more details on adequate training. Please reference [Guidance on SOPs](#) for more information on the creation and maintenance of SOPs.

#### Maintaining Process Validation:

To maintain process validation, a licensee must submit and pass a Harvest Batch or Production Batch every 30 days. If during any 30-day period, a Harvest Batch or Production Batch is not available, the first available Harvest Batch or Production Batch must be subjected to testing.

If the licensee makes a “Material Change” as described in [Rule 1-115](#) that changes their process, equipment, or SOPs in harvesting or production, the licensee must submit the next five Harvest Batches or Production Batches that the licensee produces for contaminant testing. If all tests pass, the licensee maintains their process validation status. If any of the tests fail, the licensee loses process validation.

#### Losing Process Validation:

A Regulated Marijuana Business will no longer be considered process validated under any of the following circumstances:

- If the Licensee fails to comply with the [4-100 Series of MED Rules](#), including 4-110, 4-115, 4-120.
- If the Licensee fails a contaminant test and does not submit three new passing test batches from three new Harvest or Production Batches within 30 days.
- It has been one year since the first passing Harvest or Production Batch sample was submitted towards process validation.

*To assist the industry with achieving process validation, the MED has created [flow charts linked herein](#), which are in a format that can be printed and utilized as a reference.*