

December 14, 2016

MEDICAL MARIJUANA INFORMATION BULLETIN 2016-31

Subject: Summary and Guidance for New Temporary Testing Rules

Recently, the Oregon Health Authority (OHA) adopted temporary testing rules with the intention of relieving some of the testing burden on producers and processors. Based on concerns and input from processors that the temporary testing rules adopted on December 2, 2016, were still overly burdensome, the OHA has now adopted additional temporary testing rules to address some of the concerns of stakeholders.

These rules are effective December 15, 2016, and will be valid until May 30, 2017. The temporary testing rules were not intended to overhaul the testing requirements. The intent of the temporary testing rules is to relieve some of the regulatory burden and facilitate the availability of marijuana items to the retail market and to patients. OHA will begin working on a more comprehensive review of the testing rules in the beginning of 2017.

Testing is still required to be performed by an accredited and licensed laboratory. Testing rules apply to both medical and retail marijuana items.

Below is a summary of the changes to the testing rules made effective December 15, 2016, and some general guidance on the testing rules.

The full rule text should be reviewed and may be found at: healthoregon.org/ommprules

Temporary Testing Rule Changes Effective December 15, 2016

OAR 333-007-0350: Batch Requirements

- Cannabinoid products must be separated into process lots of not larger than 35,000 unit batches, up from 1,000 unit batches.

OAR 333-007-0360: Sampling and Sample Size

OAR 333-007-0440: Control Study

- Samples from batches of usable marijuana of the same strain may be combined for purposes of testing potency regardless of the combined total weight of the multiple batches.
- The sample increments required to be collected for cannabinoid concentrates, extracts and products depend on the process lot size and have been amended in [Exhibit B, Tables 5 and 6](#).

- The sample increments required to be collected for cannabinoid concentrates, extracts, and products that have successfully passed a control study have been amended and can be found in [Exhibit B, Tables 7 and 8](#).

OAR 333-064-0110: Reporting Marijuana Test Results

- Laboratories have until January 31, 2017, to report certain quality control information on test report results.

General Guidance on Testing Rule Changes

Below is some general guidance for the transition between the old and new testing rules.

- A processor that received certification approval from OHA for process validation for a particular product may still have their certification valid for two years if:
 - (a) No changes to the standard operating procedures for that product have occurred.
 - (b) No changes in the type of ingredient in the product, except for a difference in the strain of usable marijuana, or the purity of an ingredient have occurred.
- Laboratories should use sampling increments found in [Exhibit B, Tables 7 or 8](#), for subsequent testing lots for processors that have received certification approval from OHA for process validation. Future sampling of batches should be performed as outlined in OAR 333-007-0440(9).

If a change listed above has occurred, the process validation is considered invalid and the processor must follow requirements to complete a control study if they would like.

- Any processor that completed one round of process validation may use the test results as a control study and submit the required documentation to OHA or OLCC, as appropriate. See the marijuana testing page for more information. healthoregon.org/marijuanatesting
- For tests performed after October 1, 2016, if a processor only failed a solvent test due to exceeding action levels for Butanol, Propanol, or Ethanol, that test result may be submitted to OHA for review and if approved, the test results may be used and the product may be transferred.
- The process lot size used in the control study defines the lot size that a processor must use for that product for one year.

Again, this is just a summary of the rule changes. The full rule text should be reviewed and may be found at: healthoregon.org/ommprules

For an updated full summary of the temporary testing rules please review [Bulletin 2016-30](#).