

December 14, 2016

MEDICAL MARIJUANA INFORMATION BULLETIN 2016-30 UPDATED

Subject: Summary of New Temporary Testing Rules

The Oregon Health Authority (OHA) has adopted temporary testing rules aimed at lowering the testing burden for producers and processors based on concerns and input from the marijuana industry. While the new temporary testing rules lessen the testing burden, they are still protective of public health and safety.

These rules are effective December 2, 2016 and will be valid until May 30, 2017. OHA will be working on a permanent solution to the testing issue beginning in the new year.

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

General label Requirements; Prohibitions; Exceptions: OAR 333-007-0090

- The THC and CBD amount required to be on a label must be the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100, plus or minus five percent.

Definitions: OAR 333-007-0310

- The definition of “harvest lot” has been changed to allow more than one strain and to clarify that any marijuana harvested within a 48 hour period is part of the same harvest lot if it was cultivated using the same growing practices and is cured under uniform conditions.

Batch Requirements: 333-007-0350

- Cannabinoid products must be separated into process lots of not larger than 35,000 unit batches.
- The size of a process lot of concentrates, extracts or products other than edibles, submitted for sampling and testing for purposes of a control study (see below) defines the maximum process lot size for future batch sampling and testing.

Sampling and Sample Size: OAR 333-007-0360

- Samples of different batches of usable marijuana may be combined for purposes of testing for potency if the batches are the same strain.

- Samples from multiple batches within a harvest lot may be combined for testing of pesticides if the total weight of the batches is not more than 10 pounds.
 - **Note:** If the combined sample fails pesticide testing, all the batches from which samples were taken, fail and will need to be destroyed.
- After a concentrate, extract or product has successfully completed a control study (see below) sample increments can be combined into one primary sample, and a field duplicate sample must also be taken.
- Minimum sample increments for different batch sizes or units of concentrates, extracts and products are in Exhibit B, referenced in OAR 333-007-0360.

Standards for Testing for Solvents: OAR 333-007-0410

- Butanol, Propanol and Ethanol have been removed from the solvent list.

Standards for THC and CBD Testing: OAR 333-007-0430

- The maximum concentration limit permitted in a package may have a variance of 5 percent over, but no more, as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

Control Study: OAR 333-007-0440

- Process validation is being replaced with one control study, reducing testing from three consecutive process lots to just one process lot.
- If a processor chooses to perform a control study, every cannabinoid concentrate, extract or product must successfully complete one control study every year.
- During a control study, sample increments must be tested separately to determine if the concentrate, extract or product is uniform.
- Once OHA has certified a control study, sample increments may be combined into a primary sample for testing and a field duplicate sample must be taken.
- A control study will be valid for one year unless a change to the standard operating procedure or a change in the type of ingredient is made by the processor or processing site.
 - Products that differ only in flavor or color do not need a separate control study as long as the different flavors or colors do not have an effect on the potency.

Waiver: OAR 333-007-0490

- A once a year, one time control study makes the waiver rule unnecessary and it is being repealed.

Failed Test Samples: OAR 333-007-0450

- If after a failed test a registrant wishes to have a sample reanalyzed, the registrant must request a reanalysis within 7 calendar days from the date the laboratory sent notice of the failed test. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.
- If a registrant requested a reanalysis and the sample passes, the registrant has 7 calendar days from the date the laboratory sent notice of the passed test to request that

another laboratory resample the batch and confirm the passing test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

- The registrant needs to follow OHA's instructions for reporting reanalysis and subsequent testing results.
- If a batch fails pesticide testing, it may not be destroyed without obtaining permission from the Authority.

Marijuana Item Sampling Procedures and Testing: OAR 333-064-0100

- New sampling protocols have been adopted and are referenced.

Reporting Marijuana Test Results: OAR 333-064-0110

- A test report must clearly identify whether a sample passes or fails.
- If requested by the Authority, a laboratory must report aggregate information about numbers of tests performed, number of tests where analytes are detected but are below the action limits, and de-identified pesticides and solvent testing reports where a sample passed testing but with a "detected" level.
- Laboratories have until January 31, 2017, to report certain quality control information to test report results.

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