June 14, 2017
MEDICAL MARIJUANA INFORMATION BULLETIN 2017-06

Subject: Testing Rules Guidance

This document provides guidance based on common questions related to the OHA testing rule changes. This bulletin **does not** cover all of the testing rule changes.

The most current copy of the testing rules are available on our rules webpage. Information bulletin 2017-05 provides a summary of the key changes that were made to the rules effective May 31, 2017.

Definition of "Harvest Lot"

- A specifically identified quantity of marijuana that is cultivated utilizing the same growing practice, harvested within a **72-hour period** at the same location and cured under uniform conditions.

  **Due to two conflicting definitions in the OHA rules, the above definition listed in the rules at OAR 333-007-0310, should be considered the correct definition across all rules.*

Definition of "Batch Size"

- Usable marijuana batch size has been changed from 10 pounds to **15 pounds**.

Usable Marijuana Testing Requirements

- All testing must occur within a single harvest lot. **Potency and pesticides can no longer be combined across harvest lots.**
- A harvest lot and the batches from that harvest lot can include multiple strains.
- Harvest lots (or batches) containing multiple strains must be separated into different strain specific physical containers.
- Pesticides **can** be tested across multiple strains within a batch **but licensees and registrants should work with a testing laboratory on the sampling plan**.
- Potency testing is strain specific for batches within a harvest lot.

- Producers or growers may need to have separate tests for water activity and moisture content if there are multiple strains within a batch in order to have more accurate potency results. Licensees and registrants should work with a testing laboratory on the best sampling and testing procedure for water activity and moisture content.

Usable Marijuana Testing Requirements: Prior to Transfer

- Producer or grower transferring to retailer or dispensary:
  Must be tested for **pesticides**, **moisture content/water activity** and **potency**.

- Producer or grower transferring to a processor (making an extract or concentrate):
  Must be tested for **moisture content/water activity** unless the processor is processing in a way the uses effective sterilization.

- Producer or grower transferring to a processor making a marijuana product (example: tincture made from flower material and alcohol):
  Must be tested for **pesticides** and **moisture content/water activity**.

Extract and Concentrate Testing requirements

- Every process lot of extract and concentrate must be tested for pesticides and solvents.

- Potency testing of extracts and concentrates is required if the extract or concentrate itself will ultimately be sold to a consumer or transferred to a patient.

- The solvents 2-Butanol and 2-Propanol were not removed from Exhibit A, Table 4; only Ethanol was removed.

Processor Remediation

- Processors may remediate extracts or concentrates for a failed pesticide test if and only if **all usable marijuana used in processing the lot has been tested and passed for pesticides** prior to being processed.

- A process lot of concentrates or extracts that are permitted to be remediated must be re-sampled and re-tested for pesticides.

Labeling THC and CBD on a label that will ultimately be sold to a consumer

- The THC concentration on a label cannot exceed the maximum concentration limit as determined by the Retail and Medical Concentration Limit Tables. A marijuana item labeled with a THC concentration in excess of the amount listed in the Retail Concentration Limit Table will be considered a medical-grade product and will need to be labeled as such.

However, there is a variance allowed for labeling the THC and CBD values of the marijuana item. Under OAR 333-007-0090(10), the THC and CBD amount on the label must be the value calculated by the lab plus or minus 10%.

The variance allows for the THC or CBD listed on the label to vary by 10% of the value calculated by the laboratory.

Example: If the lab value for THC was 69.5%, the variance would be as follows:

> ***10% of lab value = 0.695 x 0.10 = 0.0695***
> ***Increase lab value by 10% = 0.695 + 0.0695 = 0.7645 or 76.45%***
> ***Decrease lab value by 10% = 0.695 - 0.0695 = 0.6255 or 62.55%***

If the marijuana item has more than one laboratory test result for THC or CBD from the same batch, the THC and CBD may be expressed on the label in one of two ways:

1. The THC and CBD concentrations may be listed as a range, based on the high and low THC and CBD values for each sample that was tested; or

2. The THC and CBD concentrations may be listed as an average of all the THC values for each sample or an average of all the CBD values for each sample.

Example: If a marijuana item received three test results for THC -- 47.2%, 50.3%, and 43.5% -- the THC potency could be listed in one of two ways:

> ***Range** - the range lists the lowest lab value and the highest lab value. In this case, the following would appear on the label:*
>
> > ***THC Range: 43.5% - 50.3%***
>
> ***Average** - for the average, all of the values would be added together and then divided by the number of test results received. In this example, there are three test results so the sum of the three numbers will then be divided by three. The following would appear on the label:*
>
> > ***THC Average = (47.2 + 50.3 + 43.5) / 3 = 47.0***

If the potency on the label needs to be expressed in mg per serving and per container, the values would need to be converted into milligrams. There are 1,000 milligrams in one gram. Using the same lab values as above, one gram (or 1,000 milligrams) of extract would be converted into milligrams of THC as follows:

> *THC lowest value = 1,000 mg x 43.5% = 435 mg THC*
>
> *THC median value = 1,000 mg x 47.2% = 472 mg THC*

THC highest value = 1,000 mg x 50.3% = 503 mg THC

THC Range in milligrams: 435 mg THC - 503 mg THC

THC Average in milligrams: 470 mg THC

Research and Development (R&D) Testing

- Limited R&D testing is now allowed to be performed by an accredited and licensed laboratory for licensees and registrants.
- The R&D testing does not count as a compliance test.
- A licensee or registrant is still required to complete all needed compliance tests based on the product type before they may transfer product.
- **Producers and growers may not** have pesticide R&D testing performed on usable marijuana.
- All pesticide testing on usable marijuana is considered a compliance test.

Control Studies

- Only Processors are able to submit marijuana items for control studies.
- A processor must tell the laboratory prior to sampling, what the unit of sale is. Exhibit B, Table 6 outlines the sampling increments. A declared unit of sale for purposes of sampling does not necessarily need to be the same size that is ultimately sold. For example, a processor could choose a unit of sale for the control study that is 6 oz., and decide to sell the product in 2, 4 or 6 oz. sizes but not larger than 6 oz sizes. If a product passes a control study sampling for future process lots must be done on that same unit of sale size.

  Example: A processor makes a process lot of 20,000 capsules and informs the laboratory that the unit of sale is a container with 5 capsules each. There are 4,000 units of sale in the 20,000 capsule process lot. Therefore, 20 sample increments of the final unit of sale will need to be taken. This means 100 capsules (5 capsules x 20) from the total process lot of 20,000 will need to be sampled at a minimum. The 100 capsules will be split into 20 samples and each sample will be run individually. For a subsequent process lot after a control study has been certified, 5 capsules (the initial unit of sale) will need to be sampled for the primary sample and 5 capsules will need to be sampled for the field duplicate, for a total of 10 capsules. For the next process lot of 20,000 capsules, even if the processor wants to sell the capsules in packages of 3, a minimum of 10 capsules, 5 for the primary and 5 for the duplicate, will still need to be sampled.

Example: A processor makes a process lot of 1,000 ounces of a tincture that will be placed in a final package size of 4 ounce containers. The units of sale will be 250 units. Therefore, 8 sample increments of the final unit of sale will need to be taken. This means 32 ounces (4 oz. x 8) from the total process lot of 1,000 ounces of the tincture will need to be sampled at a minimum. The 32 ounces will be split into 8 samples and each sample will be run individually.

- Changes in a process lot size **do** invalidate a control study.
    - A processor changes the process lot from 20,000 capsules to 30,000 capsules. The processor could not apply the control study based on the 20,000 capsules to the larger process lot.
- Changes in the size of the finished product packaging **do not** invalidate a control study.
    - The smaller the unit of sale the greater chance of variability in the results. The lab may need to pull more samples as needed to ensure they have enough product to run all required test results.
    - Processor must ensure that maximum concentration limits are not exceeded.