Control Study Guidance

The purpose of a control study is to determine if a processor or processing site is using a standard operating procedure (SOP) that results in a finished cannabinoid concentrate, extract or product that is homogeneous and for cannabinoid products meets the potency target identified in the SOP. A control study must be certified by the Oregon Health Authority (OHA) or the Oregon Liquor Control Commission (OLCC). Once certified, a control study will be valid for two years from the date of certification. Only marijuana items listed and approved on the control study form will qualify for reduced testing under a control study.

This guidance will help explain the new control study rules.

Ordering a Control Study

A registered or licensed processor or processing site may order a control study to be performed on a finished cannabinoid concentrate, extract or product they have an endorsement to make. To order a control study, a control study form must be filled out by the processor or processing site and be given to the primary testing laboratory. Once certified, the processor or processing site must provide a copy of the certified control study to the laboratory that will be performing reduced testing for a marijuana item approved under a control study.

OLCC licensed wholesalers may order testing on finished concentrates, extracts, or products under a certified control study on behalf of a processor.

Control Study Form Explanation

An item undergoing a control study must have a SOP that outlines the process for making the finished concentrate, extract or product, and variations of that item that substantially follows the same procedure but results in a flavor or color variation. The SOP must be named (a number reference is acceptable as well) and contain the version number and date the SOP was created and last modified.

All Cannabinoid Concentrates, Extracts, and Products

Product category. The type/category of item being made must be listed (concentrate, extract, topical, edible, etc.). If the product is an edible, specify the type of edible it is (cookie, gummy candy, cake ball, etc.)

Texture of product. A description of the feel, appearance, or consistency of the item being made. All variations of the item that are listed on the control study form should be similar in texture. Appropriate descriptions to use here are smooth, crunchy, liquid, solid, made with toppings, etc.

Concentrate or Extract

The items described below must be listed for cannabinoid concentrates and extracts being submitted for a control study.

Batch weight. The final production weight of the concentrate or extract made that will be sampled and tested for the control study. Note that the size of a process lot submitted for sampling and testing for purposes of a control study defines the maximum process lot for that concentrate or extract for purposes of sampling and testing after a control study has been certified.

The number of servings in the unit of sale and the serving size in the unit of sale. "Unit of sale" means an amount of a marijuana item commonly packaged for transfer or sale to a consumer, patient or designated primary caregiver, or capable of being packaged for transfer or sale to a consumer, patient or designated primary caregiver. "Serving" or "serving size" means an amount of product that is suggested for a consumer or patient to use and should match the information that will be placed on the label. As long as the THC per serving size remains the same and the concentration limit requirements are met, the product may be sold in different units of sale.

Cannabinoid Products Only

The items described below must be listed for cannabinoid products being submitted for a control study.

The unit of sale and serving size. "Unit of sale" means an amount of a marijuana item commonly packaged for transfer or sale to a consumer, patient or designated primary caregiver, or capable of being packaged for transfer or sale to a consumer, patient or designated primary caregiver. "Serving" or "serving size" means an amount of product that is suggested for a consumer or patient to use. The serving size should explain the amount of product the consumer or patient should use to reach a specific potency. As long as the THC per serving size remains the same and the concentration limit requirements are met, the product may be sold in different units of sale, such as 2 items in a package or 5 items in a package or a tincture being sold in 1 ounce bottles verse 2 ounce bottles.

THC per serving. The amount of THC per serving the processor or processing site intends the cannabinoid product to have per unit of sale of the product. Products with varying concentration amounts will each need their own control study. If a processor makes a recreational product with 5 mg per serving in the unit of sale and a medical product with 50 mg per serving in the unit of sale then each product will need its own control study.

The final weight or volume of the unit of sale. The amount the product that will be packaged weights or if the product is a liquid, the volume of the product in a unit of sale.

Variation of finished concentrates, extracts and product

Only variations listed and certified by the approving Agency may have reduced testing performed on them under a certified control study.

In order to be considered a variation of a finished cannabinoid concentrate, extract or product being submitted for a control study, only the following may be changed:

- A different strain of usable marijuana.
- An ingredient with a different level of purity.
- Different flavors or colors in a batch as long as the different flavors or colors do not have an effect on the potency of the finished cannabinoid product.
- The same type or form of an ingredient in the same or substantially the same amount where the only change is the taste or color of the finished cannabinoid product, but the ingredient change does not change the texture or weight of the finished cannabinoid product. An example of this would be using milk chocolate instead of dark chocolate in making chocolate bars.

In addition, for each product, concentrate or extract variation listed on the control study form the following must be included:

- The unit of sale, the number of servings in the unit of sale and the serving size in the unit of sale. If the exact same product has more than one size container it will be sold in, all sizes per unit should be listed on the form. If a unit size is not listed, it cannot be tested under a control study once the control study is certified. Each variation made of the product must include this information.

Testing of Products, Concentrates, and Extracts

Pre-Control Study Testing
Sample increments taken for testing for a control study must be taken in accordance with Exhibit B, Table 5 or 6. Samples increments may not be combined and must be tested individually. All sample increments for pesticide and solvent testing must pass.

In order to have an item certified for potency under a control study the amount of THC between sample increments taken from the batch cannot exceed 20% RSD. In addition, for products, the amount of THC in any sample increment cannot be exceeded by more than 20% the amount of THC the processor or processing site intends the product to contain, unless the target THC is 10 mg or less. The amount or percentage of THC for any sample increment cannot exceed the maximum concentration limit permitted in a package by more than 10% as specified in the retail or medical marijuana item concentration limits permitted in OAR 333-007-0200 to 333-007-0220.

Once a control study is certified, sample increments for concentrates and extract may be collected and combined into a primary sample and a field duplicate as described in OAR 333-007-0360, Exhibit B, Table 7, OAR 333-064-0100, ORELAP-SOP-002 Rev. 3.3. For products, at a minimum, one unit of sale must be collected, at random, for the primary sample, and one unit of sale must be collected at random for the field duplicate sample. Both the primary and the field duplicate sample must be prepared and analyzed individually for any test that is requirement for the marijuana item. Both the primary and field duplicate sample must have passing test results in order for the item to be considered meeting the testing requirements.

When is a new control study needed?

A certified control study expires after two years. If a processor wishes to continue operating under a control study, it will need to go through the control study certification process again.

A control study can become invalidated if a processor makes any changes to the standard operating procedure for the concentrate, extract or product that has a certified control study. Changes may include an altered texture, a differing weight of the finished cannabinoid product, or for products, expected THC potency. A processor must report to either OHA or OLCC if a control study is invalidated. A new control study would need to be performed on a marijuana item who's control study becomes invalidated. In addition, if a processor makes a new variation of a marijuana item that is not listed on the certified control study form, this would be considered a change in SOP and a new control study would be needed.

Lastly, if a concentrate, extract, or product fails a potency test post control study, the control study will be invalidated and a new one will need to be submitted.

The control study rules can be found under OAR 333-007-0440:
healthoregon.org/ommprules

Control study forms for OHA registrants and OLCC licensees may be found on the OMMP laboratories webpage.