

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 7

MARIJUANA LABELING, CONCENTRATION LIMITS, AND TESTING

333-007-0300

Marijuana Testing: Purpose and Effective Date

(1) The purpose of these rules is to establish the minimum compliance testing standards for marijuana items. These rules are applicable to:

- (a) A licensee; and
- (b) A registrant who is not exempt from the testing requirements.

(2) The testing requirements do not apply to:

- (a) A grower if the person is transferring usable marijuana or an immature marijuana plant to:
 - (A) A patient who designated the grower to grow marijuana for the patient; or
 - (B) A designated primary caregiver or an organization or facility caregiver of the patient who designated the grower to grow marijuana for the patient; or
- (b) A designated primary caregiver or an organization or facility caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver or organization or facility caregiver.

(c) Immature plants or seeds.

(3) A person registered with the Authority under ORS 475B.785 to 475B.828 who is subject to these rules may not:

- (a) Transfer a marijuana item that is not sampled and tested in accordance with these rules; or
- (b) Accept the transfer of a marijuana item that is not sampled and tested in accordance with these rules.
- (4) A person licensed by the Commission must comply with these rules at all times.
- (5) If a registrant, who is exempt from the testing requirements, chooses to have a marijuana item tested for pesticides, the requirements of OAR 333-007-0450 and 333-007-0500 still apply.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0310

Definitions

For purposes of OAR 333-007-0300 through 333-007-0500:

(1) "Added substance" means any component or ingredient added to usable marijuana, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the finished cannabinoid product, including but not limited to flavors, non-marijuana derived terpenes, and any substances used to change the viscosity or consistency of the cannabinoid product.

~~(2)~~ "Authority" means the Oregon Health Authority.

~~(3)~~ "Batch" means:

- (a) A quantity of marijuana or usable marijuana from a harvest lot; or
 - (b) A quantity of cannabinoid concentrate or extractor cannabinoid product from a process lot.
- ~~(4)~~ "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(54) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.

(65) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(76)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana; or

(b) Usable marijuana, cannabinoid extracts and cannabinoid concentrates that have been combined with an added substance.

(c) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate or extract by itself; or

(C) Industrial hemp, as defined in ORS 571.300.

(87) "Cannabinoid capsule":

(a) Means a small, soluble pill, tablet, or container that contains liquid or powdered cannabinoid product, concentrate or extract and is intended for human ingestion.

(b) Does not mean a cannabinoid suppository.

(98) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(109) "Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of four fluid ounces or less that consists of either:

(a) A non-potable solution of at least 25 percent non-denatured alcohol, in addition to cannabinoid concentrate, extract or usable marijuana, and perhaps other ingredients intended for human consumption or ingestion that is exempt from the Liquor Control Act under ORS 471.035; or

(b) A non-potable solution comprised of glycerin, plant-based oil, or concentrated syrup; cannabinoid concentrate, extract or usable marijuana; and perhaps other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.

(110) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes transdermal patches.

(124) "Cannabis Tracking System" or "CTS" means the Oregon Liquor Control Commission's system for tracking the transfer of marijuana items and other information as authorized by ORS 475B.177.

(132) "Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(143) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

(154) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.

(165) "Chain of custody procedures" means procedures employed by laboratory personnel using a chain of custody form to record the possession of samples from the time of sampling through the retention time specified by the Authority or Commission.

(176) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.

(187) "Commission" means the Oregon Liquor Control Commission.

(198) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a marijuana item.

(2049) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient, or designated primary caregiver or organization or facility caregiver.

(210) "Control study" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through sampling and testing as described in OAR 333-007-0440.

(224) "Cured" means a process of removing moisture from marijuana under controlled environmental conditions so the moisture content is 15 percent or less.

(232) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service Number 1972-08-3.

(243)(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475B.415(5)(b).

(b) "Designated primary caregiver" does not include the person's attending physician.

(254) "Field duplicate sample" means sample increments taken in an identical manner to sample increments taken for the primary sample and representative of the same marijuana item being sampled that is prepared and analyzed separately from the primary sample.

(265) "Finished cannabinoid concentrate or extract" means a cannabinoid concentrate or extract that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.

(276) "Finished cannabinoid product" means a cannabinoid product that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids.

(287) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, chewing gum and includes beverages.

(298) "Grower" has the same meaning as "person responsible for a marijuana grow site."

(3029) "Grow site" means a specific location registered by the Authority and used by the grower to produce marijuana for medical use by a specific patient under ORS 475B.810.

(310) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location and cured under uniform conditions.

(324) "High heat" means a temperature exceeding 180 degrees Fahrenheit.

(332) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.

(343) "Human consumption or human ingestion" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.

(354) "Human use" includes human consumption or human ingestion, inhalation, topical application or any other use that allows a cannabinoid to enter the human body.

(365) "Laboratory" means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS 475B.560.

(376) "Level of quantification" means the minimum levels, concentrations, or quantities of a target variable, for example an analyte, that can be reported by a laboratory with a specified degree of confidence.

(387) "Licensee" has the meaning given that term in ORS 475B.015.

(398)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

~~(4039)~~ "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

~~(410)~~ "Marijuana processing site" means a marijuana processing site registered under ORS 475B.840.

~~(424)~~ "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.858.

~~(432)~~ "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

~~(44)~~ "Organization or facility caregiver" means:

(a) An organization that provides hospice, palliative or home health care services that:

(A) Is licensed under ORS 443.014 to 443.105, 443.305 to 443.355, or 443.850 to 443.869;

(B) Has significant responsibility for managing the well-being of a patient; and

(C) Is designated by the Authority as an additional caregiver for a patient; or

(b) A residential facility as defined in ORS 443.400 that:

(A) Is licensed under ORS 443.400 to 443.455;

(B) Has significant responsibility for managing the well-being of a patient; and

(C) Is designated by the Authority as an additional caregiver for a patient.

~~(453)~~ "Patient" has the same meaning as "registry identification cardholder."

~~(464)~~ "Person responsible for a marijuana grow site" has the same meaning as "grower" and means a person who has been selected by a patient to produce medical marijuana for the patient and who has been registered by the Authority for this purpose under ORS 475B.810.

~~(475)~~ "Process lot" means:

(a) Any amount of cannabinoid concentrate or extract of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or

(b) Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract.

~~(486)~~ "Processing" means the compounding or conversion of marijuana into cannabinoid products, or cannabinoid concentrates or extracts.

~~(497)~~ "Processing site" means a processor registered with Authority under ORS 475B.840.

~~(5048)~~ "Processor" has the meaning given that term in OAR 845-025-1015.

~~(5149)~~ "Producer" has the meaning given that term in OAR 845-025-1015.

~~(520)~~ "Producing" means:

(a) Planting, cultivating, growing, trimming or harvesting marijuana; or

(b) Drying marijuana leaves and flowers.

~~(534)~~ "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.810, 475B.840 or 475B.858.

~~(542)~~ "Registry identification cardholder" means a person who has been diagnosed by an attending physician with a debilitating medical condition and for whom the use of medical marijuana may mitigate the symptoms or effects of the person's debilitating medical condition, and who has been issued a registry identification card by the Authority under ORS 475B.797(5)(a).

~~(553)~~ "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100.

~~(564)~~ "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.

(575) "Remediation":

- (a) Means a process or technique applied to a marijuana item to remove pesticides or solvents.
- (b) Does not include dilution.

(586) "Sample" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

(597) "Sample increment" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing or, in the case of a control study, is tested individually.

(60) "Standard operating procedure" for the purposes of producing kief includes but is not limited to procedures for creating the kief, purging unwanted components from the kief, thoroughly cleaning all equipment, counters and surfaces used to produce the kief, and appropriate use of any necessary safety or sanitary equipment.

(6158) "Sterilization" means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

(6259) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.

(630) "Texture" means the feel, appearance, or consistency of a marijuana item.

(644) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.

(652) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.

(663) "These rules" means OAR 333-007-0300 through 333-007-0500.

~~(64) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish consensus standards for accrediting environmental laboratories.~~

~~(65) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab Standards (© 2009 The NELAC Institute), which describe the elements of laboratory accreditation developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies.~~

(676) "Total THC" means the molar sum of THC and THCA.

(687) "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 organization or facility caregiver, or capable of being packaged for transfer or sale to a consumer, patient, ~~or~~ designated primary caregiver or organization or facility caregiver.

(698) "Usable marijuana":

- (a) Means the dried leaves and flowers of marijuana.
- (b) Includes, for purposes of these rules, pre-rolled marijuana as long as the pre-roll consists of only dried marijuana leaves and flowers, an unflavored rolling paper and a filter or tip.
- (c) Does not include:
 - (A) The seeds, stalks and roots of marijuana; or
 - (B) Waste material that is a by-product of producing or processing marijuana.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0320

Compliance Testing Requirements for Marijuana or Usable Marijuana

- (1) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a consumer or patient prior to selling or transferring the marijuana or usable marijuana for the following:
- (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Water activity and moisture content in accordance with OAR 333-007-0420.
 - (c) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid concentrate or extract for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (3) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid product for the following:
- (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (4) A producer or grower must test one or more batches from a harvest lot of marijuana or usable marijuana for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.
- (6) A marijuana producer must test every batch from a harvest lot of marijuana or usable marijuana intended to produce kief for water activity prior to producing the kief unless the producer tests the kief for water activity per OAR 333-0070-0420.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0330

Compliance Testing Requirements for Cannabinoid Concentrates and Extracts

- (1) A processor or processing site must test every process lot of a finished cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following:
- (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
 - (c) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following, except for a cannabinoid concentrate that meets the criteria in section (6) of this rule:
- (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
- (3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:
- (a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and
 - (b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or

(c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.

(4) A processor or processing site must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(5) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

(6) A process lot of a cannabinoid concentrate that is made only using food grade animal fat or food grade plant-based oil is not required to be tested for pesticides if:

(a) All marijuana or usable marijuana used to make the concentrate was tested for pesticides and passed pesticide testing in accordance with OAR 333-007-0400; and

(b) The concentrate itself is only used to make a cannabinoid product intended for human consumption or use but not intended for inhalation and the concentrate is not sold directly to consumers or patients.

(7) Marijuana producers producing kief as permitted under OAR 845-025-2020:

(a) Must test every process lot for use by a consumer or patient prior to selling or transferring the kief for the following:

(A) Pesticides in accordance with OAR 333-007-0400.

(B) Water activity in accordance with OAR 333-007-0420.

(C) THC and CBD concentration in accordance with OAR 333-007-0430.

(b) Must test every process lot intended for use by a processor in making a cannabinoid product for the following:

(A) Pesticides in accordance with OAR 333-007-0400; and

(B) Water activity in accordance with OAR 333-007-0420.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0360

Sampling and Sample Size Requirements for Compliance Testing

(1) Marijuana or ~~U~~usable marijuana.

(a) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a processor or processing site to make a cannabinoid concentrate or extract.

(b) Sample increments taken must in total represent a minimum of 0.5 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in OAR 333-064-0100(2).

(c) A portion of sample increments taken from multiple batches of usable marijuana from the same harvest lot may be combined into one sample for purposes of testing for THC and CBD if the batches are the same strain, regardless of the size of the multiple batches.

(2) Cannabinoid concentrates, extracts and products.

(a) Samples of cannabinoid concentrates, extracts and products intended for human consumption, use or ingestion for use by a consumer or patient must be taken from the finished cannabinoid concentrate, extract or product as those terms are defined in OAR 333-007-0310.

(b) Until a control study has been certified under OAR 333-007-0440, the minimum number of sample increments that must be taken are established in Exhibit B, Table 5 or 6, incorporated by reference.

Enough sample increments from a batch must be taken to determine whether the batch is homogeneous

and must be taken in a manner consistent with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

(c) If a cannabinoid concentrate or extract has a certified control study, the minimum number of sample increments that must be taken for future batches of that concentrate or extract are established in Exhibit B, Table 7, incorporated by reference. The sample increments may be combined into a primary sample and a field duplicate sample in accordance with OAR 333-007-0440(9) and OAR 333-064-0100(2). The primary sample and the field duplicate sample must be prepared and analyzed separately.

(d) For a cannabinoid product that has a certified control study, at a minimum one unit of sale chosen at random, is required for the primary sample and one unit of sale chosen at random, is required for the field duplicate sample for testing future batches of that product in accordance with OAR 333-007-0440(9) and OAR 333-064-0100(2). The primary sample and the field duplicate sample must be prepared and analyzed separately.

(e) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

(3) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0420

Standards for Testing Water Activity and Moisture Content

(1) Usable marijuana must be tested by a laboratory for:

- (a) Water activity; and
- (b) Moisture content.

(2) Kief must be tested by a laboratory for water activity unless the marijuana or usable marijuana used to produce the kief has already passed testing for water activity prior to producing the kief in accordance with OAR 333-007-0320(6).

~~(3)~~ If a sample has a water activity rate of more than 0.65 Aw the sample fails.

~~(4)~~ If a sample has a moisture content of more than 15 percent the sample fails.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0430

Standards for THC and CBD Compliance Testing

(1) A laboratory must test for the following when testing a marijuana item for potency:

- (a) THC.
- (b) THCA.
- (c) CBD.
- (d) CBDA.

(2) A process lot of a cannabinoid concentrate, extract or product that has not successfully completed a control study fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of THC and CBD, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 20 percent RSD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100 for any sample increment, exceeds the maximum concentration limits permitted in package by over 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(3) A process lot of a cannabinoid concentrate, extract or product that has successfully completed a control study fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of THC or CBD, as calculated pursuant to OAR 333-064-0100, between the primary sample and the field duplicate exceeds 15 percent RPD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in a package by over 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable

~~(4) A sample cannot fail CBD testing.~~

~~(45) Notwithstanding subsection (2)(a) and (3)(a) of this rule:~~

~~(a), a sample A cannabinoid product~~ that has less than 5 mg of THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

~~(b) A cannabinoid product that has less than 5 mg of CBD per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.~~

~~(c) A cannabinoid concentrate or extract that has less than 5 mg THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.~~

~~(d) A cannabinoid concentrate or extract that has less than 5 mg CBD per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.~~

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0440

Control Study

The purpose of a control study is to determine if a processor or processing site is using standard operating procedures (SOP) that result in a finished cannabinoid concentrate, extract or product that is homogeneous and for cannabinoid products meets the potency target identified in the SOPs.

(1) A laboratory may perform a control study on a process lot of cannabinoid concentrates, extracts or products for a processor or processing site if the processor or processing site provides to a laboratory, in writing:

(a) A request for a control study on a form prescribed by the Authority or Commission; and

(b) For cannabinoid products provides:

(A) A reference number or name of the SOP for the product that is the subject of the control study, the version number of the SOP if applicable, and the date the SOP was created and last modified, if applicable;

(B) The amount of THC per serving the processor or processing site intends the cannabinoid product to have per unit of sale of the product;

(C) The number of uniform units of sale in the process lot;

(D) The final weight of the unit of sale;

~~(E) The unit of sale and number of servings in the unit of sale, if applicable size;~~

~~(DF)~~ Product category (examples include edible ~~and type~~, tincture, topical, capsule);

~~(E)~~ The final weight or volume of the unit of sale; and

~~(FG)~~ The texture of product.

(c) For cannabinoid concentrates and extracts provides:

(A) A reference number or name of the SOP for the concentrate or extract that is the subject of the control study, the version number of the SOP if applicable, and the date the SOP was created and last modified, if applicable;

(B) The total weight of the batch;

~~(CB)~~ The final weight ~~and volume if applicable~~, of the unit of sale, if applicable, ~~the number of servings in the unit of sale and the serving size in the unit of sale;~~

~~(DE)~~ Product category (concentrate or extract); and

~~(ED)~~ The texture of the concentrate or extract.

(d) A description of any variation of the product, concentrate or extract the processor or processing site intends to include under the control study that would be permitted under section (11) of this rule, including for each separate product, concentrate or extract the weight of the unit of sale, and the number of servings in the unit of sale, if applicable ~~and the serving size in the unit of sale.~~

(2) Sample increments taken for purposes of a control study may not be combined and must be taken in accordance with OAR 333-007-0360, Exhibit B, Table 5 or 6, incorporated by reference.

(3) Sample increments from a cannabinoid concentrate or extract must be tested for:

(a) Pesticides in accordance with OAR 333-007-0400;

(b) Solvents in accordance with OAR 333-007-0410; and

(c) THC concentration in accordance with OAR 333-007-0430 if the concentrate or extract is intended to be transferred or sold directly to a consumer or patient.

(4) Sample increments from a cannabinoid product must be tested for THC concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.

(5) During a control study a batch passes:

(a) Pesticide testing if each sample increment is below the action limit established in OAR 333-007-0400.

(b) Solvent testing if each sample increment is below the action limit established in OAR 333-007-0410; and

(c) THC and CBD concentration testing if:

(A) The amount of THC and CBD, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch does not exceed 20 percent RSD; ~~and~~

(B) For cannabinoid products, the amount of THC in any sample increment, as calculated pursuant to OAR 333-064-0100, does not exceed by more than 20 percent the amount of THC the processor or processing site intended the product to contain as described in section (1) of this rule, unless all sample increments are the target ~~THC is~~ below 10 mg THC per unit of sale in which case this paragraph does not apply; and

(C) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100 for any sample increment does not exceed the maximum concentration limit permitted in a package by more than 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(6) A laboratory must identify on a form prescribed by the Authority if a batch undergoing a control study has passed for any of the following, and must send the form at the client's request to the Authority or the Commission:

(a) Pesticides, if applicable.

(b) Solvents, if applicable.

(c) THC concentration as calculated pursuant to OAR 333-064-0100.

(7) A control study fails if:

(a) Any sample increment exceeds an action limit in OAR 333-007-0400 (Pesticides) or 333-007-0410 (Solvents).

(A) A sample increment that exceeds an action limit may not be reanalyzed and retested under OAR 333-007-0450(1) unless the laboratory determines that the result is due to laboratory error and the laboratory error is reported to the Authority or the Commission.

(B) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400, ~~or~~ 333-007-0410 may not be remediated under OAR 333-007-0450(5)(a) or (7)(c) for purposes of passing the control study.

(C) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400 or 333-007-0410 may be remediated for purposes of selling or transferring the cannabinoid concentrate, extract or product, if permitted under OAR 333-007-0450, but sample increments from that batch may not be resubmitted for a control study.

(b) The amount of THC or CBD in a cannabinoid concentrate, extract or product, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch exceeds:

(A) 20 percent RSD; or

(B) For cannabinoid products, the amount of THC the processor or processing site intended the product to contain as described in section (1) of this rule is exceeded by more than 20 percent, unless all sample increments~~the target THC are~~ below 10 mg THC per unit of sale in which case this paragraph does not apply.

(c) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100 for any sample increment, exceeds the maximum concentration limit permitted in a package by more than 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(A) A batch that has a sample increment fail under subsections (b) or (c) of this section may not be re-mixed or re-packaged under OAR 333-007-0450(~~108~~) (a) or (b) for purposes of passing the control study.

(B) A batch that has a sample increment fail under subsections (b) or (c) of this section may be re-mixed or re-packaged for purposes of selling or transferring the cannabinoid concentrate, extract or product as permitted under OAR 333-007-0450(~~108~~) (a) or (b), but sample increments from that batch may not be resubmitted for a control study.

(8) A process lot sampled and tested for purposes of a control study may be sold or transferred if the sample increments pass all the required tests.

(9) If a cannabinoid concentrate, extract or product successfully passes a control study ~~on and after January 1, 2019~~ and the control study has been certified by the Authority or the Commission, as applicable, the following applies to sampling and testing of future batches for two years except as provided in section (10) of this rule:

(a) For cannabinoid concentrates and extracts, sample increments may be collected and combined into a primary sample and a field duplicate sample as described in OAR 333-007-0360, Exhibit B, Table 7, OAR 333-064-0100, ORELAP-SOP-002 Rev. ~~4.13.3~~.

(b) For cannabinoid 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.

(c) Both the primary sample and the field duplicate sample must be prepared and analyzed individually for any test that is required for the marijuana item.

(10) The certification of a control study is invalidated:

(a) If a processor or processing site makes any changes:

(A) To the standard operating procedures for that cannabinoid concentrate, extract or product, including changes that alter the texture, weight or volume of the unit of sale, homogeneity or for products, expected THC potency.

(B) In the type of ingredient in the cannabinoid concentrate, extract or product, except as outlined in section (11) of this rule.

(b) If a cannabinoid concentrate, extract or product fails a THC or CBD test under OAR 333-007-0430~~(3)(a)~~.

(11) For purposes of subsection (10)(a) of this rule it is not considered a change to standard operating procedures or a change in the type of ingredient if the processor or processing site is using:

(a) Different strains of usable marijuana in batches.

(b) An ingredient with a different level of purity as long as the purity of the ingredient complies with the Authority's or the Commission's processing rules.

(c) Different flavors or colors in batches, as long as the different flavors or colors do not have an effect on the potency of the finished cannabinoid product.

(d) 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 does not change the texture or weight of the finished cannabinoid product.

(12) A processor or processing site does not qualify for reduced sampling and testing under a control study until either the Authority or Commission:

(a) Reviews documentation associated with the control study;

(b) Certifies the control study; and

(c) Notifies the laboratory and the processor that the control study is considered certified.

(13) If a processor or processing site does not have a certified control study it must have the cannabinoid concentrate, extract or product sampled in accordance with OAR 333-007-0360, Exhibit B, Tables 5 and 6 and the sample increments prepared and analyzed separately.

(14) Any testing performed as part of a control study is considered a compliance test.

(15) A processor or processing site must report to the Authority or the Commission if a control study is invalidated under section (10) of this rule and failure to report is a violation of these rules.

(16) This rule also applies to producers producing kief under OAR 845-025-2020.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0450

Failed Test Samples

(1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.

(a) If a registrant or licensee wishes to have a sample reanalyzed, the registrant or licensee must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the registrant or licensee. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.

(b) If a registrant or licensee has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the registrant or licensee has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the

passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

(c) A registrant or licensee must inform the Authority or the Commission immediately, of the following, in a manner prescribed by the Authority or the Commission:

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated or sterilized in accordance with this rule; or

(b) If it is not or cannot be remediated or sterilized under this rule, must be destroyed in a manner specified by the Authority or the Commission.

(3) If a registrant is permitted to remediate under this rule, the registrant must provide notice to the Authority of the registrant's intent to remediate.

(4) Except as otherwise permitted under this rule, a cannabinoid concentrate or extract that is permitted to undergo remediation cannot be further processed into a cannabinoid product during the remediation process.

(5) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.

(6) Failed microbiological contaminant testing.

(a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(b) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.

(7) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.

(8) Failed water activity or moisture content testing.

(a) If a sample from a batch of marijuana or usable marijuana fails for water activity or moisture content the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch; or

(B) Continue to dry or cure.

(b) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be sampled and tested in accordance with these rules.

(9) Failed pesticide testing.

(a) If a sample from a batch of marijuana or usable marijuana fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority or the Commission, except as permitted under subsection (c) of this section. A batch may not be destroyed without obtaining permission from the Authority or the Commission.

(b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample of usable marijuana failed a pesticide test.

(c) If a sample from a batch of marijuana or usable marijuana fails pesticide testing but only for the analytes piperonyl butoxide or pyrethrins, and the Oregon Department of Agriculture determines that the products used were listed on the Department's Guide List for Pesticides and Cannabis and the product was applied in accordance with the label, the Authority or the Commission may permit the producer or grower to remediate the usable marijuana using procedures that would reduce the concentration of pesticides to less than the action level. A batch of usable marijuana that is permitted to be remediated must be re-sampled and re-tested for pesticides in accordance with these rules.

(d) If a processor or a processing site is only processing with marijuana or usable marijuana that has passed pesticide testing under OAR 333-007-0320 and a sample from a batch of a cannabinoid concentrate or extract fails pesticide testing the batch may be remediated using procedures that would reduce the concentration of pesticides to less than the action level.

(e) A batch that is remediated in accordance with subsection (d) of this section must be re-sampled and re-tested in accordance with these rules. A batch that is remediated but after being re-sampled and re-tested fails pesticide testing must be destroyed as ordered by the Authority or the Commission.

(10) Failed potency testing.

(a) A marijuana item that fails potency testing under OAR 333-007-0430(2)(b) or (3)(b) may be repackaged in a manner that enables the item to meet the concentration limit standards in OAR 333-007-0210 and 333-007-0220, as applicable. A marijuana item that is repackaged in accordance with this subsection must be re-sampled and re-tested in accordance with these rules.

(b) A marijuana item that fails potency testing under OAR 333-007-0430(2)(a) or (3)(a) may be re-mixed in an effort to meet the standards in OAR 333-007-0430(2)(a) or (3)(a). A marijuana item that is re-mixed must be re-sampled and re-tested in accordance with these rules.

(11) If a sample fails a test after undergoing remediation or sterilization as permitted under this rule the batch must be destroyed in a manner approved by the Authority or the Commission.

(12) A registrant must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.

(13) A registrant must, as applicable:

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

(14) If a batch fails a test under these rules a registrant:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.

Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

333-007-0480

Audit and Random Testing

(1) The Authority may require a registrant to submit samples identified by the Authority to a laboratory of the ~~registrant~~ Authority's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0500 or any other rule of the Authority.

(2) A laboratory doing audit testing under section (1) of this rule must comply with these rules unless otherwise authorized by the Authority.

(3) The Authority may, at any time, require a registrant to permit the sampling of or submit a sample of a marijuana item to the Authority for testing. Such testing may include testing for:

(a) Any microbiological contaminant.

(b) Heavy metals;-

(c) ~~Other Solvents;~~

(d) Pesticides;

(e) Adulterants, additives, or other contaminants that may pose a risk to public health and safety, or are prohibited by law.

(4) The Authority may require any testing ordered under sections (1) and (3) of this rule to be paid for by the registrant.

(5) The Authority may obtain a marijuana item from a registrant at any time and have it tested to ensure compliance with these rules and OAR chapter 333, division 8, or to protect the public health and safety.

Statutory/Other Authority: ORS 475B.555 ~~& EO 19-09~~

Statutes/Other Implemented: ORS 475B.555 ~~& EO 19-09~~

333-007-0500

Quality Control and Research and Development Testing

(1) A registrant or a licensee may request that a laboratory conduct testing for the purpose of assuring quality control or for research and development, except as provided in section (2) of this rule.

(2) A ~~grower or producer~~ registrant or a licensee may not request that a laboratory conduct pesticide testing on a marijuana item for the purpose of quality control or for research and development. A pesticide test on a marijuana item is considered by the Authority and the Commission to be a compliance test.

(3) A registrant or licensee that submits a marijuana item for quality control or research and development testing is not subject to OAR 333-007-0320 to 333-007-0470.

(4) A laboratory result from a quality control or research and development test cannot be used as a compliance test result and a marijuana item that has only undergone a quality control or research and development test may not be transferred or sold, unless the marijuana item is not required to have a compliance test before being transferred or sold.

(5) Registrants and licensees must maintain and retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Authority or the Commission.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555