

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

**DIVISION 7**

**Cannabis Testing**

**333-007-0300**

**Purpose and Effective Date**

(1) The purpose of these rules is to establish the minimum 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 of the patient who designated the grower to grow marijuana for the patient; or

(b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.

(3) A person registered with the Authority under ORS 475B.400 to 475B.525 who is subject to these rules may not:

(a) Transfer a marijuana item on or after October 1, 2016, that is not sampled and tested in accordance with these rules; or

(b) Accept the transfer of a marijuana item on or after October 1, 2016, 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) Notwithstanding section (3)(a) of this rule, until January 1, 2017, a dispensary may transfer a marijuana item to a patient or caregiver that was transferred to the dispensary before October 1, 2016, and that was not sampled and tested in accordance with these rules if the item contains a label placed on the package where it can easily be seen by the patient or caregiver that reads "DOES NOT MEET NEW TESTING REQUIREMENTS" in 12 point font, and in bold, capital letters.

(6) Nothing in these rules prevents a registrant from having marijuana items sampled and tested in accordance with these rules by an accredited and licensed laboratory prior to October 1, 2016.

(7) Prior to October 1, 2016, an accredited laboratory performing sampling or testing for a registrant may comply with this rule or OAR 333-008-1190 but the laboratory must identify on the test result which rule the results are compliant with.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0310**

#### **Definitions**

For purposes of OAR 333-007-0300 through 333-007-0490:

- (1) "Authority" means the Oregon Health Authority.
- (2) "Batch" means:
  - (a) A quantity of usable marijuana from a harvest lot; or
  - (b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.
- (3) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.
- (4) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.
- (5) "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.
- (6)(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.
- (b) "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.
- (7) "Cannabinoid capsule":
  - (a) Means a small soluble container, usually made of gelatin that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.
  - (b) Does not mean a cannabinoid suppository.
- (8) "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.
- (9) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.
- (10) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes transdermal patches.
- (11) "Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.
- (12) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.
- (13) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.
- (14) "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.
- (15) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.
- (16) "Commission" means the Oregon Liquor Control Commission.
- (17) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.
- (18) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid)

of cannabis, Chemical Abstracts Service Number 1972-08-3.

(19)(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.

(20) "Field duplicate sample" means a sample taken in an identical manner from and representative of the same marijuana item being sampled that is analyzed separately, that is used for quality control only.

(21) "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, or chewing gum.

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

(23) "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.420.

(24) "Harvest lot" means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time at the same location and cured under uniform conditions.

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

(26) "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.

(27) "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.

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

(29)(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.

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

(31) "Marijuana processing site" means a marijuana processing site registered under ORS 475B.435.

(32) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.450.

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

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

(35) "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.420.

(36) "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 as defined in subsection (a) of this section.
- (37) "Process validation" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through a series of sampling and testing from three consecutive process lots as described in OAR 333-007-0440.
- (38) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extracts.
- (39) "Processing site" means a processor registered with Authority under ORS 475B.435.
- (40) "Processor" has the meaning given that term in OAR 845-025-1015.
- (41) "Producer" has the meaning given that term in OAR 845-025-1015.
- (42) "Producing" means:
- (a) Planting, cultivating, growing, trimming or harvesting marijuana; or
  - (b) Drying marijuana leaves and flowers.
- (43) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.420, 475B.435 or 475B.450.
- (44) "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.415(5)(a).
- (45) "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..
- (46) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.
- (47) "Sample" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.
- (48) "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.
- (49) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.
- (50) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.
- (51) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978- 85-0.
- (52) "These rules" means OAR 333-007-0300 through 333-007-0490.
- (53) "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.
- (54) "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.

- (55) "Total THC" means the molar sum of THC and THCA.
- (56)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.
- (b) "Usable marijuana" 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. Stat. Auth.: ORS 475B.555
- Stats. Implemented: ORS 475B.555

### **333-007-0315**

#### **Ordering Tests**

A registrant or licensee must provide a laboratory, prior to laboratory taking samples, with the following:

- (1) A written request of analysis for each test the laboratory is being requested to conduct.
  - (2) Notification of whether the batch is being re-sampled because of a failed test and the failed test results.
  - (3) Certification of successful process validation, if applicable, on a form prescribed by the Authority.
  - (4) Proof of a waiver under OAR 333-007-0490, if applicable. Stat. Auth.: ORS 475B.555
- Stats. Implemented: ORS 475B.555

### **333-007-0320**

#### **Testing Requirements for Marijuana or Usable Marijuana**

- (1) A producer or grower must test every 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 harvest lot of marijuana or usable marijuana intended for use by a processor or processing site 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 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.
  - (4) 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. Stat. Auth.: ORS 475B.555
- Stats. Implemented: ORS 475B.555

### **333-007-0330**

#### **Testing Requirements for Cannabinoid Concentrates and Extracts**

- (1) A processor or processing site must test every process lot of 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:

- (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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0340**

#### **Testing Requirements for Cannabinoid Products Intended for Human Consumption or Ingestion and Cannabinoid Suppositories**

(1) A processor or processing site must test every process lot of a cannabinoid product intended for human consumption or ingestion, including cannabinoid edibles, capsules, and tinctures, and cannabinoid suppositories for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.

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

(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule 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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

**333-007-0345**

**Testing Requirements for Cannabinoid Topicals and Cannabinoid Transdermal Patches**

- (1) A processor or processing site must test every process lot of a cannabinoid topical or transdermal patch for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test a process lot of a cannabinoid topical or transdermal patch for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule 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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

**333-007-0350**

**Batch Requirements**

- (1) Usable marijuana.
    - (a) A producer or grower must separate each harvest lot into no larger than 10 pound batches.
    - (b) Notwithstanding subsection (1)(a) of this rule, a producer or grower may combine harvest lots together for purposes of having a batch sampled if each batch is intended for use by a processor or processing site to make a cannabinoid concentrate or extract and each harvest lot was:
      - (A) Cultivated utilizing the same growing practices and grown in close proximity on the licensed or registered premises;
      - (B) Harvested at the same time; and
      - (C) If cured prior to sampling, cured under uniform conditions.
    - (c) A producer or grower may not combine harvest lots into a batch for purposes of sampling and testing for THC or CBD.
    - (d) If harvest lots are combined in accordance with subsection (1)(b) of this rule the batch must be labeled so that it identifies the different harvest lots that were combined.
  - (2) Cannabinoid concentrates and extracts and cannabinoid products. A process lot is considered a batch.
  - (3) A grower and processing site must assign each batch a unique batch number and that unique batch number must be:
    - (a) Documented and maintained in the grower and processing site records for at least two years and available to the Authority upon request;
    - (b) Provided to the individual responsible for taking samples; and
    - (c) Included on the batch label as required in OAR 333-007-0380.
  - (4) A grower and processing site may not reuse a unique batch number. Stat. Auth.: ORS 475B.555
- Stats. Implemented: ORS 475B.555

**333-007-0360**

**Sampling and Sample Size**

(1) 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) Samples 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).

(2) Cannabinoid concentrates, extracts and products.

(a) Unless a cannabinoid concentrate, extract or product has successfully passed process validation, enough samples from a batch must be taken to ensure that the required attributes in the batch to be tested are homogenous and consistent with the laboratory's accredited sampling policies and procedures described in OR 333-064-0100(2).

(b) If a cannabinoid concentrate, extract or product has successfully passed process validation only a primary sample and field duplicate sample must be taken from a batch in accordance with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0370**

#### **Sampling Personnel Requirements; Sampling Recordkeeping**

(1) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples.

(2) Sampling may be conducted at a licensee's or registrant's premises or the licensee or registrant may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.

(3) Laboratory personnel that perform sampling must:

(a) Follow the laboratory's accredited sampling policies and procedures;

(b) Follow chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8; and

(c) After taking samples document the samples in accordance with OAR 333-064-0100(2) and if sampling for a licensee record the sampling and transfer information in the Commission's seed to sale system, as required by the Commission.

(4) A laboratory must maintain the documentation required in these rules for at least two years and must provide that information to the Authority upon request.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0380**

#### **Grower and Processing Site Requirements for Labeling, Storing, and Securing Pre-Tested Marijuana Items; Recordkeeping**

(1) Following samples being taken from a harvest or process lot batch a grower or processing site must:

(a) Label the batch with the following information:

(A) The registrant's registration number;

(B) The harvest or process lot unique identification number;

- (C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;
  - (D) The test batch or sample unique identification numbers supplied by the laboratory personnel;
  - (E) The date the samples were taken; and
  - (F) In bold, capital letters, no smaller than 12 point font, "PRODUCT NOT TESTED."
- (b) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported.
  - (c) Be able to easily locate a batch stored and secured under section (1)(b) of this rule and provide that location to the Authority or a laboratory upon request.
- (2) If the samples pass testing the product may be sold or transferred in accordance with the applicable Authority rules.
- (3) If the samples do not pass testing the grower or processing site must comply with OAR 333-007-0450.
- Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0390**

#### **Standards for Testing Microbiological Contaminants**

- (1) A marijuana item required to be tested for microbiological contaminants must be sampled using appropriate aseptic technique and tested by a laboratory for total coliform count.
- (2) If a laboratory detects the presence of any coliforms the sample must be assessed for *Escherichia coli* (*E. coli*).
- (3) A batch fails microbiological contaminant testing if the laboratory detects the presence of *E. coli* at more than 100 colony forming units per gram in a sample:
  - (a) During an initial test where no reanalysis is requested; or
  - (b) Upon reanalysis as described in OAR 333-007-0450(1). Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0400**

#### **Standards for Testing Pesticides**

- (1) A marijuana item required to be tested for pesticides must be tested by a laboratory for the analytes listed in Exhibit A, Table 3, incorporated by reference. [Table not included. See ED. NOTE.]
- (2) A batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action levels listed in Exhibit A, Table 3 in a sample:
  - (a) During an initial test where no reanalysis is requested; or
  - (b) Upon reanalysis as described in OAR 333-007-0450(1). [Table not included. See ED. NOTE.]
- (3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.  
[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]  
Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0410**

#### **Standards for Testing Solvents**

(1) A marijuana item required to be tested for solvents must be tested by a laboratory for the analytes listed in Exhibit A, Table 4 incorporated by reference. [Table not included. See ED. NOTE.]

(2) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) Detects the presence of a solvent above the action level listed in Exhibit A, Table 4 in a sample; or [Table not included. See ED. NOTE.]

(b) Calculates a RPD of more than 20 percent between the field primary result of the sample and the field duplicate result.

(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years.

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: ORS 475B.555

Stats. 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) If a sample has a water activity rate of more than 0.65  $A_w$  the sample fails.

(3) If a sample has a moisture content of more than 15 percent the result must be reported to the licensee but the sample does not fail.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0430**

#### **Standards for THC and CBD 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 process validation 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, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 30 percent RSD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in package 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 process validation 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, as calculated pursuant to OAR 333-064-0100, between the sample and the field duplicate exceeds 20 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 as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(4) A sample cannot fail CBD testing.

(5) Notwithstanding section (2)(a) and (3)(a) of this rule, a sample that has less than 5 mg of THC as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in section (2)(a) or (3)(a) of this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0440**

#### **Process Validation**

(1) A laboratory may perform process validation tests on three consecutive process lots of cannabinoid concentrates, extracts or products for a processor or processing site if the processor or processing site informs the laboratory, in writing:

(a) That sampling and testing is for the purposes of process validation; and

(b) For cannabinoid products, the expected THC range for the product.

(2) Samples taken for purposes of process validation testing may not be combined.

(3) Samples of cannabinoid concentrate and extracts must be tested for:

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

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

(4) Samples of cannabinoid products must be tested for THC concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.

(5) During process validation a batch passes:

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

(b) Solvent testing if:

(A) Each sample is below the action limit established in OAR 333-007-0410; and

(B) The results above the LOQ are not greater than 30 percent RSD between samples.

(c) THC concentration testing if:

(A) The amount of THC, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch does not exceed 30 percent RSD; and

(B) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100, does not exceed the maximum concentration limit permitted in a package 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 process validation has passed for any of the following:

(a) Pesticides, if applicable.

(b) Solvents, if applicable.

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

(7) A process lot sampled and tested for purposes of process validation may be sold or transferred if the samples pass all the required tests.

(8) A processor or processing site must undergo process validation for a product again or must have batches sampled and tested as if the product had not undergone process validation

if:

- (a) There are any changes to the standard operating procedures for that product.
  - (b) There are any 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.
- (9) Process validation is only valid for two years. Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0450**

#### **Failed Test Samples**

- (1) If a sample fails any initial test the laboratory that did the testing may reanalyze the sample. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.
- (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 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.
- (4) Failed microbiological contaminant testing.
  - (a) If a sample from a batch of 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.
- (5) 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 sampled and 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.
- (6) Failed water activity testing.
  - (a) If a sample from a batch of usable marijuana fails for water activity the batch from which the sample was taken may:

- (A) Be used to make a cannabinoid concentrate or extract; 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.
  - (7) Failed pesticide testing.
    - (a) If a sample from a batch fails pesticide testing the batch may not be remediated and must be destroyed in a manner approved by the Authority or the Commission.
    - (b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample failed a pesticide test.
  - (8) Failed potency testing.
    - (a) A marijuana item that fails potency testing under OAR 333-007-0430(2)(a) or (3)(a) may be repackaged in a manner that enables the item to meet the standard in OAR 333-007-0430(2)(a) or (3)(a).
    - (b) A marijuana item that is repackaged in accordance with this section must be sampled and tested in accordance with these rules.
  - (9) 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.
  - (10) An Authority representative must witness the destruction of a batch if destruction is required by this rule.
  - (11) 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.
  - (12) 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.
- Stat. Auth.: ORS 475B.555  
Stats. Implemented: ORS 475B.555

### **333-007-0470**

#### **Tentative Identification of Compounds**

- (1) Tentatively Identified Compounds (TICs) are compounds detected in a sample using gas chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis.
- (2) The Authority may initiate an investigation of a registrant upon receipt of a TICS report from a laboratory and may require a registrant to submit samples for additional testing, including testing for analytes that are not required by these rules, at the registrant's expense.

Stat. Auth.: ORS 475B.555

Stats. 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's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0490, and may require additional

testing that is not required by these rules.

(2) A laboratory doing audit testing must comply with these rules, to the extent they are applicable, and if conducting testing not required by these rules, may only use Authority approved methods.

(3) The Authority must establish a process for the random testing of marijuana items for microbiological contaminants that ensures each registrant tests every product for microbiological contaminants at least once a year.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0490**

#### **Waiver of Sampling and Testing Requirements**

(1) Solvent testing.

(a) The Commission or the Authority may, upon receipt of a written request from a licensee or registrant, waive a requirement that every batch of a process lot be tested for solvents, if the licensee or registrant can demonstrate that none of the batches from any of the previous four process lots tested failed a solvent test.

(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.

(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver and how long the waiver will be in effect.

(d) If the Commission or the Authority waives the testing requirement the licensee or registrant is subject to random testing and the Commission or the Authority shall notify the licensee or registrant when a process lot must be tested in accordance with these rules.

(2) Sampling.

(a) The Commission or the Authority may, upon receipt of a written request from a processor or processing site waive the sampling requirements in OAR 333-007-0360(2)(a) for a particular product if the processor processing site:

(A) Can demonstrate that none of the batches from any of the previous four process lots tested failed any test;

(B) Submits to the Commission or the Authority detailed processing standard operating procedures that demonstrate the product is uniform and uniform from process lot to process lot;

(C) Can demonstrate that it has and follows quality control measures; and

(D) Can demonstrate that subjecting a product to process validation under OAR 333-007-0440 is cost prohibitive.

(b) In order to qualify for a waiver under this section the fourth process lot must be processed at least 30 days after the first.

(c) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee of the waiver, how long the waiver will be in effect, and the sampling that is required of the product for which the waiver was approved.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555