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RULES:
333-007-0310, 333-007-0315, 333-007-0370, 333-007-0430, 333-007-0450, 333-007-0480, 333-007-0600

AMEND: 333-007-0310

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0310
Definitions amendments are mostly housekeeping in nature such as placing them in alphabetical order and removing definitions that are not used in the text of the rules. In addition, a new definition for “Cannabis Reference Laboratory” is being added due to the passage of HB 2931 in the 2023 legislative session (2023 OL Ch. 519) and a definition for “Total CBD” is being added to provide clarity as to what that term means in the rules. Definitions for “Remediation” and “Sterilization” are being expanded to provide additional clarity to the context of the rules within division 7.

CHANGES TO RULE:

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) "Adult use cannabinoid" includes, but is not limited to, tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, the optical isomers of delta-8-tetrahydrocannabinol or delta-9-tetrahydrocannabinol and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.¶
(3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae. ¶
(b) "Artificially derived cannabinoid" does not include:¶
(A) A naturally occurring chemical substance that is separated from the plant Cannabis family Cannabaceae by a

chemical or mechanical extraction process;¶
(B) Cannabinoids that are produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst; or¶
(C) Any other chemical substance identified by the Commission, in consultation with the Authority and the Department of Agriculture, by rule.¶
(4) "Authority" means the Oregon Health Authority.¶
(5) "Batch" means:¶
(a) A quantity of marijuana or usable marijuana from a harvest lot; or¶
(b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.¶
(6) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.¶
(7) "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.¶
(8) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.¶
(~~8~~9) "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.¶
(~~9~~10)(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.¶
~~(10) "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.¶~~
(11) "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.¶
(12) "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 consisting 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.¶
(13) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes a cannabinoid transdermal patch~~es~~.¶
(14) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.¶
(14~~5~~) "Cannabis" means the plant species Cannabis sativa and in these rules refers to all forms of the plant regardless of total delta-9-THC content and may also be used to refer to processed products that contain marijuana or industrial hemp.¶
(16) "Cannabis reference laboratory" means the Oregon Department of Agriculture cannabis testing laboratory.¶
(15~~7~~) "Cannabis Tracking System" or "CTS" means the Oregon Liquor and Cannabis Commission's system for tracking the transfer of marijuana items or industrial hemp-derived vapor item and other information as authorized by ORS 475C.177.¶
~~(16) Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.¶~~
(~~17~~8) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.¶
(1~~8~~9) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.¶
~~(19) "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, Commission or Department of Agriculture.~~¶
~~(20) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.~~¶
(~~21~~20) "Commission" means the Oregon Liquor and Cannabis Commission.¶
(2~~2~~1) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a marijuana item or industrial hemp-derived vapor item.¶
(2~~3~~2) "Consumer" has the meaning given that term in ORS 475C.009 and does not include a patient, designated primary caregiver or organization or facility caregiver.¶
(24~~3~~) "Cured" means a process of removing moisture from marijuana under controlled environmental conditions so the moisture content is 15 percent or less.¶
(2~~5~~4) "Delta-8-tetrahydrocannabinol" or "~~D~~delta-8-THC" means (6aR, 10aR)-6,6,9-trimethyl-3-pentyl6a,7,10,10a-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.¶
(2~~6~~5) "Delta-9-tetrahydrocannabinol" or "~~D~~delta-9-THC" means (6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H- benzo[c]chromen-1-ol., Chemical Abstracts Service Number 1972-08-3.¶
(2~~7~~6) "Delta-9-tetrahydrocannabinolic acid" or "delta-9-THCA" means (6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-2- carboxylic acid, Chemical Abstracts Service Number 23978-85-0.¶
(2~~8~~7)(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 475C.783(5)(b).¶
(b) "Designated primary caregiver" does not include the person's attending physician.¶
(2~~9~~8) "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 or industrial hemp-derived vapor item being sampled that is prepared and analyzed separately from the primary sample.¶
(~~30~~29) "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.¶
(3~~1~~0) "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.¶
(3~~2~~1) "Finished inhalable cannabinoid product" means a cannabinoid product that is intended for human use via inhalation, 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.¶
(3~~3~~2) "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.¶
(3~~4~~) ~~"Grower" has the same meaning as "person responsible for a marijuana grow site."~~¶
(~~35~~3) "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 475C.792.¶
(3~~6~~4) "Grower" has the same meaning as "person responsible for a marijuana grow site."¶
(35) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a seven calendar-day period at the same location and cured under uniform conditions.¶
(3~~7~~) ~~"High heat" means a temperature exceeding 180 degrees Fahrenheit.~~¶
(~~38~~6) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.¶
(3~~9~~7) "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.¶
(~~40~~38) "Human use" includes human consumption or human ingestion, inhalation, topical application or any other use that allows a cannabinoid to enter the human body.¶
(~~41~~39) "Industrial hemp" has the meaning given that term in ORS 571.269.¶
(~~42~~0) "Industrial hemp-derived vapor item" means an industrial hemp concentrate or industrial hemp extract, as those terms are defined in ORS 571.269, whether alone or combined with other substances, that is intended for use in an inhalant delivery system.¶
(~~43~~1) "Inhalant delivery system" has the meaning given that term in ORS 431A.175.¶
(~~44~~2) "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 and Cannabis Commission under ORS 475C.548.¶
(45) ~~"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.~~¶

(463) "Licensee" has the meaning given that term in ORS 475C.009.¶
(474)(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.¶
(485) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.¶
(496) "Marijuana processing site" means a marijuana processing site registered under ORS 475C.815.¶
(5047) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475C.833.¶
(5148) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.¶
(5249) "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.¶
(530) "Patient" has the same meaning as "registry identification cardholder."¶
(541) "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 475C.792.¶
(552) "Process lot" means:¶
(a) Any amount of cannabinoid concentrate or extract or industrial hemp-derived vapor item of the same type that is homogeneous 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.¶
(563) "Processing" means:¶
(a) The compounding or conversion of marijuana into cannabinoid products, or cannabinoid concentrates or extracts.¶
(b) The compounding or conversion of industrial hemp into industrial hemp concentrates or industrial hemp extracts.¶
(574) "Processing site" means a processor registered with Authority under ORS 475C.815.¶
(585) "Processor" has the meaning givenmeans a marijuana processor, as that term in OAR 845-025-101s defined in ORS 475C.009, that holds a license issued under ORS 475C.085.¶
(596) "Producer" has the meaning given that term in OAR 845-025-1015.¶
(60) "Producing" means:¶
(a) Planting, cultivating, growing, trimming or harvesting marijuana; or¶
(b) Drying marijuana leaves and flowers.¶
(6157) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475C.792, 475C.815 or 475C.833.¶
(6258) "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 475C.783(5)(a).¶
(6359) "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.¶
(640) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.¶
(651) "Remediation":¶
(a) Means a process or technique applied to a marijuana item or industrial hemp-derived vapor item to remove, destroy, or eliminate heavy metals, pesticides, microbiological contaminants, or solvents.¶
(b) Does not include dilution.¶
(662) "Replicate sample" means a sample in addition to the primary and duplicate samples that consists of the same number of increments taken in the same manner as the primary and duplicate samples.¶

(6~~7~~3) "Sample" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.¶
(68~~4~~) "Sample increment" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing.¶
(6~~9~~5) "Standard operating procedure" means:¶
(a) A written set of instructions or procedures using the same ingredients, methods and steps to create a single type of marijuana item or industrial hemp-derived vapor item.¶
(b) 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.¶
(~~70~~66) "Sterilization" means the removal, destruction, or elimination of all microorganisms and other pathogens from a marijuana item or industrial hemp-derived vapor item by treating it with approved chemicals, subjecting it to ~~high heat~~a temperature exceeding 180 degrees Fahrenheit, or other process.¶
(67~~1~~) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.¶
(~~72~~68) "Texture" means the feel, appearance, or consistency of a marijuana item or industrial hemp-derived vapor item.¶
~~(73) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.¶~~
~~(74) "THCA" means tetrahydrocannabinolic acid, and has the same meaning as delta-9 THCa.¶~~
(~~75~~69) "These rules" means OAR 333-007-0300 through 333-007-0500.¶
(7~~6~~0) "Total ~~delta-9-tetrahydrocannabinol" or~~CBD" means the sum of the concentration or mass of CBDA multiplied by 0.877 plus the concentration or mass of CBD.¶
(71) "Total delta-9-~~-~~THC" means the sum of the concentration or mass of delta-9-THCA multiplied by 0.877 plus the concentration or mass of delta-9-THC.~~.~~¶
(7~~7~~2) "Unit of sale" means an amount of a marijuana item or industrial hemp-derived vapor item commonly packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver, or capable of being packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver.¶
(78~~3~~) "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 475C.544, ORS 475C.540
Statutes/Other Implemented: ORS 475C.544, ORS 475C.540

AMEND: 333-007-0315

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0315

This rule is being amended to add that if a wholesaler is requesting testing on behalf of another registrant or licensee, that the wholesaler must provide their license number and name along with the license number and name of the registrant or licensee.

CHANGES TO RULE:

333-007-0315
Ordering Tests ¶

(1) To request a compliance test a requestor must provide a laboratory, prior to laboratory taking samples, with at a minimum, the following information as applicable:¶
(a) The registrant or licensee's registrant or license number.¶
(b) The name, address and contact information of the registrant or licensee.¶
(c) If a registrant, whether the registrant is subject to tracking in CTS, under OAR chapter 333, division 8.¶
(d) Type of marijuana item or industrial hemp-derived vapor item.¶
(e) Harvest lot number that is associated with the batch numbers, if applicable.¶
(f) Process lot number that is associated with the batch numbers, if applicable.¶
(g) Batch numbers to be sampled.¶
(h) Total mass or volume of each batch to be sampled.¶
(i) For cannabinoid products, all intended units of sale.¶
(j) Identification of the test or tests the laboratory is being requested to conduct.¶
(k) Whether the test or tests being requested are compliance tests.¶
(l) Whether the test or tests being requested are for quality control, research and development, or any other purpose other than a compliance test.¶
(m) Whether a batch is being re-sampled because of a failed test, the date the failed test result was received by the registrant or licensee and laboratory identification number of the laboratory that conducted the initial test.¶
(n) Whether the marijuana item or industrial hemp-derived vapor item was remediated if remediation is permitted under OAR 333-007-0450.¶
(o) If a wholesaler is requesting a test on behalf of another registrant or licensee, the wholesaler must provide in addition to their own license number and name, the registration or license number and name of that registrant or licensee. ¶
(2) If the registrant or licensee informs a laboratory that a marijuana item or industrial hemp-derived vapor item is being re-sampled after a failed test, the registrant or licensee must provide the laboratory with documentation of the failed test as applicable.¶
(3) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.¶
(4) A registrant or licensee may only order a compliance test for a marijuana item that the registrant or licensee has produced or processed, as applicable, except a wholesaler who may order a compliance test.¶
(5) More than one compliance test for the same marijuana item or industrial hemp-derived vapor item may not be ordered.¶
(6) It is a violation of these rules for a registrant or licensee to:¶
(a) Fail to provide the information required in these rules to the laboratory; or¶
(b) Submit false or misleading information to a laboratory or a directed agent to submit false or misleading information to a laboratory.¶
(7) Once a test order has been submitted to a laboratory by a registrant or licensee and at least one test has already been performed, the order may not be canceled unless written permission is given by the Oregon Liquor and Cannabis Commission, the Oregon Health Authority or the Department of Agriculture.
Statutory/Other Authority: ORS 475C.544
Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0370

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0370

This rule is being amended to clarify the entire batch must be transported to a cannabis testing laboratory if sampling is to take place at the laboratory. Rule language that is redundant is also being deleted.

CHANGES TO RULE:

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 only be conducted at a licensee's or registrant's premises or the licensee or registrant may transport the entire batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.¶
~~(3) If a producer or wholesaler transports marijuana or usable marijuana to a laboratory for compliance testing for pesticides all the batches from the harvest lot must be transported so the laboratory can choose which batches to sample from.~~
Statutory/Other Authority: ORS 475~~B~~C.5~~55~~44
Statutes/Other Implemented: ORS 475~~B~~C.5~~55~~44

AMEND: 333-007-0430

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0430

This rule is being amended to align text with updated definition for total CBD.

CHANGES TO RULE:

333-007-0430
Standards for Adult Use Cannabinoid and CBD Compliance Testing ¶

(1) A laboratory must test for all of the following analytes when testing a marijuana item or industrial hemp-derived vapor item for potency:¶
(a) Delta-9-THC.¶
(b) Delta-9-THCA.¶
(c) ~~On and after July 1, 2022, d~~Delta-8-THC.¶
(c) CBD.¶
(d) CBDA.¶
(2) A process lot of a cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item 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 delta-8-THC, total delta-9-THC or total CBD, as calculated pursuant to OAR 333-064-0100, between the primary sample and the duplicate sample exceeds 10 percent RPD or between the primary sample, duplicate sample and any replicate samples exceeds 10 percent RSD; or¶
(b) The amount or percentage of delta-8-THC, total delta-9-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 the Oregon Liquor and Cannabis Commission's concentration limit rules in OAR chapter 845, division 26, as applicable.¶
(3) Notwithstanding subsection (2)(a) of this rule:¶
(a) A cannabinoid product that has less than 5 mg of total delta-9-THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶
(b) A cannabinoid product that has less than 10 mg of total CBD per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶
(c) A cannabinoid product that has less than 5 mg of delta-8-THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶
(d) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 5 mg total delta-9-THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶
(e) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 10 mg total CBD per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶
(f) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 5 mg delta-8-THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.
Statutory/Other Authority: ORS 475C.544
Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0450

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0450

This rule is being amended to clarify that retesting may not be performed at a laboratory under the same ownership as the original laboratory and may not be performed by the subcontracted laboratory that performed the first test.

This rule is being amended to further clarify which tests need to be retested if a test fails and an item is remediated.

This rule is being amended to allow for an item that fails microbiological testing to be further processed if it fails for microbiological contaminants after undergoing a remediation process.

This rule is being amended to allow for marijuana or useable marijuana that fails for heavy metals to be used to make a cannabinoid concentrate or extract if the processing method effectively decreases the presence of heavy metals below the action limit. Finished inhalable cannabinoid products and industrial hemp-derived vapor items will continue to not be allowed to be remediated.

This rule is also adopting new language that would clarify that a batch must remain in its original quantity as it was initially submitted for testing and may not be subdivided for reanalysis or retesting and that a failed batch cannot be combined with other batches as part of remediation or further processing.

CHANGES TO RULE:

333-007-0450
Failed Test Samples ¶

(1) If a sample or a 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 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 ~~wishe~~request**s** 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. The second laboratory performing the retesting:¶
(~~c~~A) ~~A registrant or licensee must inform the Authority or the Commission~~May not be performed at a laboratory under the same ownership as the original laboratory that performed the testing. ¶
(B) May not be done by a laboratory that was subcontracted to do the original testing.¶
(C) May only conduct retesting for the compliance test that initially failed.¶
(c) If reanalysis in accordance with subsection (1)(a) or retesting in accordance with subsection (1)(b) is ordered, then the batch must remain in its original quantity as it was initially submitted to the laboratory for testing and may not be subdivided.¶
(d) A registrant must inform the Oregon Health Authority (Authority) 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.~~¶

(b) Must be destroyed in a manner specified by the Authority or the Oregon Liquor and Cannabis Commission (Commission) ~~I~~if it is not or cannot be remediated or sterilized under this rule~~, must be destroyed in a manner specified by the Authority~~.¶
(c) May not be combined with other batches as part of remediation or ~~the Commission.~~further processing. ¶
(3) If a registrant is permitted to remediate or sterilize under this rule, the registrant must provide notice to the Authority of the registrant's intent to remediate or sterilize.¶
(4) Except as otherwise permitted under this rule, a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item 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 either:¶
(A) Be remediated using a sterilization process; or¶
(B) 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, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item 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 remediated through a sterilization process in accordance with subsection (a) or (b) of this section must be sampled in accordance with OAR 333-007-0360 and must be tested for~~ m~~:¶
(A) Microbiological contaminants~~, s~~;¶
(B) Solvents if required per OAR 333-007-0410~~, p~~; ¶
(C) Pesticides~~, h~~;¶
(D) Water activity and moisture content if required per OAR 333-007-0420;¶
(E) Potency in accordance with OAR 333-007-0430(1);¶
(F) Heavy metals if the marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after March 1, 2023~~,~~; and~~ m~~¶
(G) Mycotoxins if the marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after July 1, 2022.¶
(d) A batch that fails microbiological contaminant testing after undergoing remediation through a sterilization process in accordance with ~~subsection (a) or (b~~paragraph (a)(A) of this section must be destroyed in a manner specified by the Authority or the Commission, or may be further processed as described in paragraph (a)(B) of this section.¶
(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~~OAR 333-007-0360 and must be re-tested for~~ solvents, pesticides, adult use cannabinoids and CBD, h~~;¶
(A) Solvents;¶
(B) Pesticides;¶
(C) Potency in accordance with OAR 333-007-0430(1);¶
(D) Heavy metals if the marijuana item or industrial hemp-derived vapor item was manufactured on or after March 1, 2023~~, m~~;¶
(E) Mycotoxins if the marijuana item or industrial hemp-derived vapor item was manufactured on or after July 1, 2022~~,~~; and~~ m~~¶
(F) Microbiological contaminants if the marijuana item or industrial hemp-derived vapor item was manufactured on and after March 1, 2023.¶
(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 re-sampled in accordance with OAR 333-007-0360 and re-tested for ~~p~~:¶
(A) Pesticides~~, w~~;¶
(B) Water activity and moisture content~~, adult use cannabinoids and CBD, h~~;¶
(C) Potency in accordance with OAR 333-007-0430(1);¶
(D) Heavy metals if the marijuana or usable marijuana was harvested on or after March 1, 2023~~, m~~;¶
(E) Mycotoxins if the marijuana or usable marijuana was harvested on or after July 1, 2022~~,~~; and ~~m~~¶
(F) Microbiological contaminants if the marijuana or usable marijuana was harvested on and after March 1, 2023.¶
(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 in accordance with OAR 333-007-0360 and re-tested for ~~p~~:¶
(A) Pesticides ~~in accordance with these rules~~;¶
(B) Water activity and moisture content;¶
(C) Potency in accordance with OAR 333-007-0430(1);¶
(D) Microbiological contaminates if the marijuana item was harvested on or after March 1, 2023;¶
(E) Heavy metals if the marijuana item was harvested on or after March 1, 2023; and ¶
(F) Mycotoxins if the marijuana item was harvested on or after July 1, 2022.¶
(d) If a processor or a processing site is only processing with marijuana or usable marijuana that has passed pesticide testing in accordance with OAR 333-007-0400 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) If a batch of industrial hemp-derived vapor item fails pesticides testing, it may only be remediated using procedures that would reduce the concentration of pesticides to less than the action level if the input material used to make the industrial hemp-derived vapor item passed pesticide testing in accordance with OAR 333-007-0400.¶
(f) A batch that is remediated in accordance with subsection (d) or (e) of this section must be re-sampled in accordance with OAR 333-007-0360 and re-tested for ~~p~~:¶
(A) Pesticides~~, adult use cannabinoids and CBD, s~~;¶
(B) Potency in accordance with OAR 333-007-0430(1);¶
(C) Solvent testing if required per OAR 333-007-0410~~, h~~;¶
(D) Heavy metals ~~if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023, mycotoxins if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022, and microbiological contaminants if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on and after March 1, 2023.~~; ¶
(E) Mycotoxins; and ¶
(F) Microbiological contaminants.¶
(g) If a sample from a batch of finished inhalable cannabinoid products fails pesticide testing, the batch may not be remediated and must be destroyed in a manner specified by the Authority or the Commission.¶
(h) 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 or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-0430(2)(b) may be repackaged in a manner that enables the item to meet the concentration limit standards in the Commission's concentration limit rules in OAR chapter 845, division 26, as applicable. A marijuana item or industrial hemp-derived vapor 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 or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-

0430(2)(a) may be re-mixed ~~in an effort~~ to meet the standards in OAR 333-007-0430(2)(a). A marijuana item or industrial hemp-derived vapor item that is re-mixed must be re-sampled in accordance with OAR 333-007-0360 and re-tested ~~for pesticides, adult use cannabinoids and CBD, s~~in accordance with these rules for the marijuana item or industrial hemp-derived vapor item for:¶
(A) Pesticides;¶
(B) Potency in accordance with OAR 333-007-0430(1);¶
(C) Solvent testing if required per OAR 333-007-0410~~, h~~;¶
(D) Heavy metals if the marijuana item or industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023~~, m~~;¶
(E) Mycotoxins if the marijuana item or industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022~~,~~; and~~ m~~¶
(F) Microbiological contaminants if the marijuana item or industrial hemp-derived vapor item is or was manufactured on and after March 1, 2023.¶
(11) Failed heavy metal testing.~~¶~~
(a) If a sample from a batch of ~~a~~ marijuana~~,~~ or usable marijuana~~, finished inhalable cannabinoid product, or industrial hemp-derived vapor item~~ fails heavy metal testing, the batch may ~~not~~ be remediated ~~and must be destroyed~~by processing into a ~~m~~canner ~~specified by the Authority, Commiss~~abinoid concentrate or extract if the processing method reduces the concentration~~, or the Department of Agriculture.~~f heavy metals to less than the action levels. ¶
(b) If a sample from a cannabinoid concentrate or extract fails heavy metal testing, the batch may be remediated using procedures that would reduce the concentration of heavy metals to less than the action level.¶
(c) If a sample from a batch of finished inhalable cannabinoid product or industrial hemp-derived vapor item fails for heavy metals, the batch may not be remediated and must be destroyed in a manner specified by the Authority or Commission. ¶
(d) A batch that is remediated in accordance with subsection (a) or (b) of this section must be re-sampled in accordance with OAR 333-007-0360 and re-tested for ~~p~~:¶
(A) Pesticides~~, s~~;¶
(B) Solvents if required under OAR 333-007-0410~~, adult use cannabinoids and CBD, h~~;¶
(C) Potency in accordance with OAR 333-007-0430(1);¶
(D) Heavy metals~~, m~~;¶
(E) Mycotoxins ~~if the concentrate or extract was manufactured on or after July 1, 2022, and microbiological contaminants if the concentrate or extract was manufactured on and after March 1, 2023~~; and.¶
(F) Microbiological contaminants.¶
(~~d~~e) A batch that fails heavy metal testing that is not remediated ~~or that fails testing after remediation~~ must be destroyed in a manner specified by the Authority, Commission, or the Department of Agriculture.¶
(12) Failed mycotoxin testing. If a sample from a batch of a marijuana item or industrial hemp-derived vapor item fails mycotoxin testing the batch may not be remediated and must be destroyed in a manner specified by the Authority, Commission, or the Department of Agriculture.¶
(13) ~~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, Commission, or the Department of Agriculture.¶~~
~~(14)~~ 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.¶
(1~~5~~4) 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.¶
(1~~6~~5) 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 475C.544
Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0480

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Amend OAR 333-007-0480

This rule is being amended to include the rule reference for OAR 333-007-0600 and the cannabis reference laboratory.

CHANGES TO RULE:

333-007-0480
Audit and Random Testing ¶

(1) The ~~Authority~~Oregon Health Authority (Authority) may require a registrant to submit samples identified by the Authority to a laboratory of the Authority's choosing or the cannabis reference laboratory to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0~~5~~600 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) Solvents;¶
(d) Pesticides;¶
(e) Mycotoxins;¶
(f) Adulterants, additives, or other contaminants that may pose a risk to public health or safety, or is 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 475C.544
Statutes/Other Implemented: ORS 475C.544

ADOPT: 333-007-0600

NOTICE FILED DATE: 01/28/2024

RULE SUMMARY: Adopt OAR 333-007-0600

Due to the passage of HB 2931 in the 2023 legislative session new rule language is being adopted regarding the cannabis reference laboratory.

CHANGES TO RULE:

333-007-0600
Cannabis Reference Laboratory
(1) The Oregon Health Authority (Authority) may request that the cannabis reference laboratory conduct any of the following:¶
(a) Audit testing as described in OAR 333-007-0480; or¶
(b) Testing if the Authority has reason to believe the marijuana item, industrial hemp or hemp item is not in compliance with ORS 475C.544 or these rules.¶
(2) The Authority may consider a test conducted by the cannabis reference laboratory to be a compliance test.¶
(3) If a test conducted by the cannabis reference laboratory indicates a sample fails to comply with concentration limits in OAR chapter 845, division 26 or an action level in OAR chapter 333, division 7, the Authority may invalidate the results of the test conducted by the original laboratory. If the Authority invalidates a compliance test result:¶
(a) The Authority must notify the registrant who ordered the compliance test.¶
(b) The registrant must follow the applicable procedures under OAR 333-007-0450 regarding failed test samples.¶
(c) Subject to any reanalysis conducted pursuant to OAR 333-007-0450, the Authority may require the recall of any marijuana items, industrial hemp or hemp items associated with a failed sample that have been sold or transferred. The recall must be conducted in accordance with instructions provided by the Authority. The registrant must either:¶
(A) Destroy the affected marijuana items, industrial hemp, or hemp items; or¶
(B) Remediate the affected marijuana items, industrial hemp, or hemp items in accordance with OAR 333-007-0450.¶
(4) The Authority may request or require a recall based on the cannabis reference laboratory audit testing.
Statutory/Other Authority: ORS 475C.523
Statutes/Other Implemented: ORS 475C.523