PERMANENT ADMINISTRATIVE ORDER

- PH 282-2018
- CHAPTER 333
- OREGON HEALTH AUTHORITY
- PUBLIC HEALTH DIVISION

FILING CAPTION: Marijuana Labeling and Testing; Medical Marijuana Growers, Processors, Dispensaries and Grow Site Administrators

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RULES:

333-007-0010, 333-007-0200, 333-007-0300, 333-007-0310, 333-007-0315, 333-007-0330, 333-007-0340, 333-007-0345, 333-007-0350, 333-007-0360, 333-007-0400, 333-007-0410, 333-007-0420, 333-007-0430, 333-007-0440, 333-007-0450, 333-007-0500, 333-007-2000, 333-008-0010, 333-008-0638, 333-008-1610, 333-064-0025, 333-064-0100, 333-064-0110, 333-064-0120, 333-064-0130

AMEND: 333-007-0010

RULE TITLE: Labeling: Applicability

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending rule to outline transition authority for cannabis labeling rules from OHA to OLCC.

RULE TEXT:

(1) Effective January 1, 2018, the Oregon Liquor Control Commission (Commission) was given authority to adopt labeling rules under ORS 475B.605. The Commission has adopted such rules and on and after August 15, 2018, all labels submitted to the Commission for review and approval must

comply with the Commission's labeling rules in OAR chapter 845, division 25. OAR 333-007-0010(4) to (7) through 333-007-0100 only apply to the extent that marijuana items were approved by the Commission and labeled prior to the Commission's rules going into effect.

(2) For registrants who are required to comply with the Commission's labeling rules:

(a) All marijuana items transferred for sale to a patient or designated primary caregiver on or after April 1, 2019, must be labeled according to the Commission's rules.

(b) On and after January 1, 2020, marijuana items may not be sold, offered for sale, or transferred to a patient, or designated primary caregiver that do not comply with the Commission's labeling rules.

(3) On April 1, 2019 OAR 333-007-0010 through 333-007-0100 are repealed.

(4) The purpose of OAR 333-007-0010 through 333-007-0100 is to set the minimum standards for the labeling of marijuana items that are sold to a consumer, patient or designated primary caregiver. These minimum standards are applicable to:

(a) A Commission licensee as that is defined in OAR 845-025-1015; and

(b) A person registered with the Authority under ORS 475B.785 to 475B.949 who is not exempt from the labeling requirements as described in section (5) of this rule.

(5) The labeling requirements in these rules do not apply to:

(a) A grower if the grower 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.

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

(6) Nothing in these rules prohibits the Commission or the Authority from:

(a) Imposing additional labeling requirements in their respective rules governing licensees and registrants as long as those additional labeling requirements are not inconsistent with these rules; or

(b) Requiring licensees or registrants to provide informational material to a consumer, patient or designated primary caregiver at the point of sale.

(7) A person licensed by the Commission must comply with these rules at all times.

STATUTORY/OTHER AUTHORITY: ORS 475B.605

STATUTES/OTHER IMPLEMENTED: ORS 475B.605

AMEND: 333-007-0200

RULE TITLE: Concentration and Serving Size Limits: Definitions, Purpose, Scope and Effective Date

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending language for concentration limits to make consistent with similar rule found in OLCC rules for labeling.

RULE TEXT:

(1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:

(a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and

(b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.

(2) OAR 333-007-0200 through 333-007-0220 apply to:

(a) A Commission licensee as that is defined in OAR 845-025-1015; and

(b) A person registered with the Authority under ORS 475B.875 to 475B.949 who is not exempt under ORS 475B.630.

(3) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.

(4) A cannabinoid product or cannabinoid concentrate or extract meets the concentration limits permitted under OAR 333-007-0210 through 333-007-0220 if the THC as calculated in accordance

with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent.

(5) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0220.

(6) For purposes of OAR 333-007-0200 through 333-007-0220:

(a) The definitions in OAR 333-007-0310 apply unless otherwise specified.

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

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

(d) "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.

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

(f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.

(g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.

(h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:

(A) Intuitively determine how much of the product constitutes a single serving; and

(B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.

STATUTORY/OTHER AUTHORITY: ORS 475B.625

STATUTES/OTHER IMPLEMENTED: ORS 475B.625

AMEND: 333-007-0300

RULE TITLE: Marijuana Testing: Purpose and Effective Date

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Clarifies language that if a registrant submits a marijuana item for pesticides testing and it fails, that the fail needs to be reported to OMMP.

RULE TEXT:

(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 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.

(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

AMEND: 333-007-0310

RULE TITLE: Definitions

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amend definitions to be consistent with definitions found in OLCC rules.

RULE TEXT:

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

(1) "Authority" means the Oregon Health Authority.

(2) "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.

(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; 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.

(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 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 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.

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

(11) "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.

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

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

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

(15) "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.

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

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

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

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

(20) "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.

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

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

(23)(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.

(24) "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.

(25) "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.

(26) "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.

(27) "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.

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

(29) "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.

(30) "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.

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

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

(33) "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.

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

(35) "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.

(36) "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.

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

(38)(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.

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

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

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

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

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

(44) "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.

(45) "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

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

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

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

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

(50) "Producing" means:

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

(b) Drying marijuana leaves and flowers.

(51) "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.

(52) "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).

(53) "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.

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

(55) "Remediation":

(a) Means a process or technique applied to a marijuana item to remove pesticides or solvents.

(b) Does not include dilution.

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

(57) "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.

(58) "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.

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

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

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

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

(63) "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.

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

(67) "Unit of sale" means an amount of a marijuana item commonly packaged for transfer or sale to a consumer, patient or designated primary caregiver, or capable of being packaged for transfer or sale to a consumer, patient or designated primary caregiver.

(68) "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

AMEND: 333-007-0315

RULE TITLE: Ordering Tests

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adopting language stating that it is a violation for a registrant or licensee to fail to provide information to a laboratory or submit false information to a laboratory.

RULE TEXT:

(1) A registrant or licensee must provide a laboratory, prior to laboratory taking samples, with at a minimum, the following information:

(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.

(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, the unit 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 quality control or research and development tests.

(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 has a certified control study or a control study is being requested.

(o) Whether the marijuana item was remediated, if remediation is permitted under OAR 333-007-0450.

(2) If a registrant or licensee is requesting a control study the request must be submitted on a form prescribed by the Authority or Commission, as specified in OAR 333-007-0440.

(3) If the registrant or licensee informs a laboratory that a marijuana item is being re-sampled after a failed test or has a certified control study, the registrant or licensee must provide the laboratory with documentation of the failed test or certified control study as applicable.

(4) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.

(5) 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.

(6) A registrant or licensee may not order more than one compliance test for the same marijuana item.

(7) 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.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0330

RULE TITLE: Compliance Testing Requirements for Cannabinoid Concentrates and Extracts

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adopting new testing standards for a concentrate that is made only using animal fat or vegetable oil.

RULE TEXT:

(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.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0340

RULE TITLE: Compliance Testing Requirements for Cannabinoid Products

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending rule to include cannabinoid topicals and transdermal patches which was once found in OAR 333-007-0345.

RULE TEXT:

(1) A processor or processing site must test every process lot of a finished cannabinoid product intended for human consumption, use or ingestion 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 finished cannabinoid product intended for human consumption, use or ingestion 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 referenced 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.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

REPEAL: 333-007-0345

RULE TITLE: Compliance Testing Requirements for Cannabinoid Topicals and Cannabinoid Transdermal Patches

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Repealed. Rule language being reorganized and moved to be included in OAR 333-007-0340.

RULE TEXT:

(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.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0350

RULE TITLE: Batch Requirements for Compliance Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adding clarifying language that the size of a process lot submitted for sampling and testing for a control study defines the maximum process lot for that product for future testing.

RULE TEXT:

(1) Marijuana or usable marijuana. A producer or grower must separate each harvest lot of marijuana or usable marijuana into no larger than 15 pound batches.

(2) Cannabinoid concentrates and extracts.

(a) A process lot of a cannabinoid concentrate or extract is considered a batch.

(b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that concentrate or extract for purposes of sampling and testing after a control study has been certified.

(3) Cannabinoid products.

(a) A processor or processing site must separate process lots into not larger than 35,000 unit of sale batches.

(b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that product for purposes of sampling and testing after a control study has been certified.

(4) 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.

(5) A grower and processing site may not reuse a unique batch number.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0360

RULE TITLE: Sampling and Sample Size Requirements for Compliance Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Clarifying that sample size and that samples being taken for testing must be from the finished cannabinoid concentrate, extract, or product. Includes amendments to Exhibit B.

RULE TEXT:

(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) 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 homogenous 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

OAR 333-007-0360, Exhibit B

Table 5 — Sample increments per batch size of cannabinoid concentrates and extracts.

Batch Weight				Sample Increments Required
Pounds		**Kilograms**		
0-0.50	0.50-1.5	0-0.23	0.24-0.68	4 8
1.51-3.00		0.69-1.36		12
3.10-6.00		1.40-2.72		16
6.10-10.00		2.77-4.54		20
10+		4.58+		32

Table 6 — Sample increments per batch size of cannabinoid products.

Units for Sale	Sample Increments
2-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201 — 35,000	20

Table 7 - Sample increments per batch size of cannabinoid concentrates and extracts for the primary sample and field duplicate if concentrate or extract has certified control study.

Batch Weight		Sample Increments Required	
Pounds	Kilograms	Primary	Field Duplicate
0-0.50	1-0.23	2	2
0.50-1.5	0.24-0.68	4	4
1.51-3.00	0.69-1.36	6	6
3.10-6.00	1.40-2.72	8	8
6.10-10.00	2.77-4.54	10	10
10+	4.58+	16	16

AMEND: 333-007-0400

RULE TITLE: Standards for Pesticides Compliance Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Clarifying that a batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action limits in any sample, including the field duplicate.

RULE TEXT:

(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 attached.]

(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 any sample, including a field duplicate:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1).

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

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

Exhibit A

OAR 333-007-0400:*Table 3. Pesticide analytes and their action levels*

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2

Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins [1]	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins [2]	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

OAR 333-007-0410:*Table 4. List of solvents and their action levels*

Solvent	Chemical Abstract Services (CAS) Registry Number	Action Level (µg/g)
1,4-Dioxane	123-91-1	380
2-Butanol	78-92-2	5000
2-Ethoxyethanol	110-80-5	160
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butanes	See [3]	5000 [4]
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
Hexanes	See [5]	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Pentanes	See [6]	5000
Propane	74-98-6	5000 [7]
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes	See [8]	2170 [9]

[1] Permethrins should be measured as cumulative residue of cis-and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

[2] Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

[3] Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

[4] Limit based on similarity to pentanes

[5] Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

[6] Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

[7] Limit based on similarity to pentanes

[8] Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

[9] The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

AMEND: 333-007-0410

RULE TITLE: Standards for Solvents Compliance Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Reducing the relative percent difference (RPD) that must be calculated between a primary and field duplication sample for solvent testing from 20% to 15%

RULE TEXT:

(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 attached.]

(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

(b) Calculates a RPD of more than 15 percent between the field primary result and the field duplicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4.

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

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

Exhibit A

OAR 333-007-0400:*Table 3. Pesticide analytes and their action levels*

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4

Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins [1]	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins [1]	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

[1] Permethrins should be measured as cumulative residue of cis-and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

[2] Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

OAR 333-007-0410:*Table 4. List of solvents and their action levels*

Solvent	Chemical Abstract Services (CAS) Registry Number	Action Level (µg/g)
1,4-Dioxane	123-91-1	380
2-Butanol	78-92-2	5000
2-Ethoxyethanol	110-80-5	160
2-Propanol (IPA)	67-63-0	5000
Acetone	67-64-1	5000
Acetonitrile	75-05-8	410
Benzene	71-43-2	2
Butanes	See [3]	5000 [4]
Cumene	98-82-8	70
Cyclohexane	110-82-7	3880
Dichloromethane	75-09-2	600
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Ethylene glycol	107-21-1	620
Ethylene Oxide	75-21-8	50
Heptane	142-82-5	5000
Hexanes	See [5]	290
Isopropyl acetate	108-21-4	5000
Methanol	67-56-1	3000
Pentanes	See [6]	5000
Propane	74-98-6	5000 [7]
Tetrahydrofuran	109-99-9	720
Toluene	108-88-3	890
Xylenes	See [8]	2170 [9]

[3] Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

[4] Limit based on similarity to pentanes

[5] Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

[6] Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

[7] Limit based on similarity to pentanes

[8] Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

[9] The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

AMEND: 333-007-0420

RULE TITLE: Standards for Testing Water Activity and Moisture Content

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending to state that a sample fails for moisture content if it contains more than 15%.

RULE TEXT:

(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 Aw the sample fails.

(3) 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

AMEND: 333-007-0430

RULE TITLE: Standards for THC and CBD Compliance Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Reducing the relative standard deviation (RSD) from 30% to 20% between samples taken for potency testing and the relative percent difference (RPD) from 20% to 15% between the primary and field duplicate samples taken for potency testing.

RULE TEXT:

(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, 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, 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, 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.

(5) Notwithstanding subsection (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 subsection (2)(a) or (3)(a) of this rule.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0440

RULE TITLE: Control Study

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending language to detail parameters regarding a control study.

RULE TEXT:

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 unit of sale and serving size;

(D) Product category (edible and type, tincture, topical, capsule);

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

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

(C) Product category (concentrate or extract); and

(D) 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 unit of sale, the number of servings in the unit of sale 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 concentration testing if:

(A) The amount of THC, 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 the target THC is below 10 mg 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 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; and

(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 not exceeded by more than 20 percent, unless the target THC is below 10 mg 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, 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 repackaged under OAR 333-007-0450(8)(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(8)(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. 3.3.

(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 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.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-007-0450

RULE TITLE: Failed Test Samples

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adding language outlining that if an item fails for moisture content that it may be used to make a concentrate or extract or may be continued to be dried or cured.

RULE TEXT:

(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 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 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; 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 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 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 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 retested 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

AMEND: 333-007-0500

RULE TITLE: Quality Control and Research and Development Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Clarifying that pesticide testing is not allowed to be performed on quality control or research and development testing for marijuana items.

RULE TEXT:

(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 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 marijuana 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

REPEAL: 333-007-2000

RULE TITLE: OLCC Licensee Pesticide Testing Requirements

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Repealing rule language because laboratory pesticide testing capacity has increased eliminating the need to allow for OLCC licensees to perform reduced pesticide testing.

RULE TEXT:

(1) Notwithstanding OAR 333-007-0320, the Commission may establish the frequency of pesticide testing required by a producer or wholesaler as long as at least one-third of the batches in a harvest lot are tested. The producer or wholesaler must permit the laboratory that conducts the sampling to choose the batches to sample from and may not direct the laboratory to sample from specific batches.

(2) If any sample taken from a batch in accordance with section (1) of this rule fails a pesticide test, every batch from the harvest lot must be tested for pesticides.

(3) If all samples from each randomly chosen batch of a harvest lot pass pesticide testing, the entire harvest lot is considered to have passed pesticide testing and may be transferred or sold.

(4) A laboratory cannot be considered to be in violation of any accreditation standard for reporting test results in accordance with this rule.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

AMEND: 333-008-0010

RULE TITLE: Definitions

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amend definitions to be consistent with definitions found in OLCC rules.

RULE TEXT:

For the purposes of OAR chapter 333, division 8 the following definitions apply unless otherwise indicated:

(1) "Advertising" means publicizing the trade name of a PRMG, registered processing site or dispensary together with words or symbols referring to marijuana or publicizing the brand name of marijuana or a medical cannabinoid product, concentrate or extract in any medium.

(2) "Applicant" means, as applicable to the registration being applied for:

(a) An individual applying for a registry identification card under ORS 475B.797.

(b) An individual applying for a grow site registration under ORS 475B.810.

(c) A person applying for a marijuana processing site registration under ORS 475B.840.

(d) A person applying for a medical marijuana dispensary registration under ORS 475B.858.

(3) "Attending physician" means a Doctor of Medicine (MD) or Doctor of Osteopathy (DO), licensed under ORS chapter 677, who has primary responsibility for the care and treatment of a person diagnosed with a debilitating medical condition.

(4) "Attending physician statement" or "APS" means the form, prescribed by the Authority and signed by an attending physician, that states the individual has been diagnosed with a debilitating medical condition and that the medical use of marijuana may mitigate the symptoms or effects of the individual's debilitating medical condition.

(5) "Authority" means the Oregon Health Authority.

(6) "Business day" means Monday through Friday excluding legal holidays.

(7) "CBD" means cannabidiol.

(8) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(9) "Cannabinoid concentrate" means a substance obtained by separating cannabinoids from marijuana by:

(a) A mechanical extraction process;

(b) A chemical extraction process using a nonhydrocarbon-based solvent, such as vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol;

(c) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure; or

(d) Any other process authorized in these rules.

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

(11) "Cannabinoid extract" means a substance obtained by separating cannabinoids from marijuana by:

(a) A chemical extraction process using a hydrocarbon-based solvent, such as butane, hexane or propane; or

(b) A chemical extraction process using the hydrocarbon-based solvent carbon dioxide, if the process uses high heat or pressure.

(12) "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.

(13) "Cartoon" means any drawing or other depiction of an object, person, animal, creature or any similar caricature that satisfies any of the following criteria:

(a) The use of comically exaggerated features;

(b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or

(c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.

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

(15) "Common ownership" means any commonality between individuals or legal entities named as applicants or persons with a financial interest in a registration or a business proposed to be registered.

(16) "Conviction" means an adjudication of guilt upon a verdict or finding entered in a criminal proceeding in a court of competent jurisdiction.

(17) "Database" means the electronic system established pursuant to ORS 475B.879, in which the Authority stores the information PRMGs, registered processing sites and dispensaries are required to submit under these rules.

(18) "Debilitating medical condition" means:

(a) Cancer, glaucoma, a degenerative or pervasive neurological condition, positive status for human immunodeficiency virus or acquired immune deficiency syndrome, or a side effect related to the treatment of those medical conditions;

(b) A medical condition or treatment for a medical condition that produces, for a specific patient, one or more of the following:

(A) Cachexia;

(B) Severe pain;

(C) Severe nausea;

(D) Seizures, including but not limited to seizures caused by epilepsy; or

(E) Persistent muscle spasms, including but not limited to spasms caused by multiple sclerosis;

(c) Post-traumatic stress disorder; or

(d) Any other medical condition or side effect related to the treatment of a medical condition adopted by the Authority by rule or approved by the Authority pursuant to a petition filed under OAR 333-008-0090.

(19) "Delivery" has the meaning given that term in ORS 475B.791.

(20)(a) "Designated primary caregiver" means an individual who:

(A) Is 18 years of age or older;

(B) Has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and

(C) Is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority.

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

(21) "Direct interest" means an interest that is held in the name of the individual.

(22) "Domicile" means the place an individual intends as his or her fixed place of abode or habitation where he or she intends to remain and to which, if absent, the individual intends to return.

(23) "Elementary school" means a learning institution containing any combination of grades Kindergarten through 8.

(24) "Employee":

(a) Means any individual, including an alien, employed for remuneration or under a contract of hire, written or oral, express or implied, by an employer.

(b) Does not mean an individual who volunteers or donates services performed for no remuneration or without expectation or contemplation of remuneration as adequate consideration for the services performed for a religious or charitable institution or a governmental entity.

(25) "Flowering" means that a marijuana plant has formed a mass of pistils measuring greater than two centimeters wide at its widest point.

(26) "Food stamps" means the Supplemental Nutrition Assistance Program as defined and governed by ORS 411.806 through 411.845.

(27) "Grandfathered grow site" means a grow site registered by the Authority that has been approved by the Authority under OAR 333-008-0520 that can have up to:

(a) 24 mature marijuana plants and 48 immature marijuana plants that are 24 inches or more in height if the location is within city limits and zoned residential; or

(b) 96 mature marijuana plants and 192 immature marijuana plants that are 24 inches or more in height if the location is within city limits but not zoned residential or not within city limits.

(28) "Grow site" means a location registered under ORS 475B.810 where marijuana is produced for use by a patient or, with permission from a patient, for transfer to a registered processing site or dispensary.

(29) "Grow site registration card" means a card issued by the Authority that identifies the address of a marijuana grow site and the PRMG.

(30) "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.

(31) "Human consumption" 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.

(32) "Immature marijuana plant" means a marijuana plant that is not flowering.

(33) "Indirect interest" means:

(a) An interest that is owned by a business entity that is owned, in whole or in part and either directly or indirectly, through one or more other intermediate business entities, by the individual; or

(b) An interest held in the name of another but the benefits of ownership of which, the individual is entitled to receive.

(34) "Individual who has a financial interest" in a business entity that owns a processing site or dispensary means:

(a) If the business entity is a corporation:

(A) Stockholders: Any individual who owns, directly or indirectly, 10 percent or more of the outstanding stock of such corporation.

(B) Directors: Any director of the corporation who receives compensation for acting in that capacity or who owns, directly or indirectly, 5 percent or more of the outstanding stock of such corporation.

(C) Officers: Any officer of the corporation who receives compensation for acting in that capacity or who owns, directly or indirectly, 5 percent or more of the outstanding stock of such corporation.

(b) If the business entity is a trust:

(A) Trustees: Any individual who is a trustee of the trust and who receives compensation for acting in that capacity and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a trustee of the trust and that receives compensation for acting in that capacity.

(B) Beneficiaries: Any individual who is entitled to receive, directly or indirectly, income or benefit from the trust.

(c) If the business entity is a partnership:

(A) General Partners: Any individual who is a general partner of the partnership and who receives compensation for acting in that capacity or who owns 5 percent or more of the ownership interests of the partnership and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a general partner of the partnership and that receives compensation for acting in that capacity or owns 5 percent or more of the ownership interests of the partnership.

(B) Limited Partners: Any individual who is a limited partner of the partnership and who owns 10 percent or more of the ownership interests of the partnership and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a limited partner of the partnership and that owns 10 percent or more the ownership interests of the partnership.

(d) If the business entity is a joint venture: Any individual who is entitled to receive, directly or indirectly, income or benefit from the joint venture.

(e) If the business entity is a limited liability company:

(A) Managers: Any individual who is a manager of the limited liability company and who receives compensation for acting in that capacity or who owns 5 percent or more of the ownership interests of the limited liability company and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a manager of the limited liability company and that receives compensation for acting in that capacity or owns 5 percent or more of the ownership interests of the limited liability company.

(B) Members: Any individual who is a member of the limited liability company and who owns 10 percent or more of the ownership interests of the limited liability company and any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a member of the limited liability company and that owns 10 percent or more of the ownership interests of the limited liability company.

(f) Immediate family members: Any person, 18 years of age or older, involved in a marijuana processing site or dispensary, in any capacity, who is a member of the immediate family of any individual who otherwise has a financial interest in the business entity that owns the marijuana processing site or dispensary. A person is a member of the immediate family of the individual if the person receives more than 50 percent of his or her financial support from that individual.

(g) Landlord: Any individual who is a landlord of a processing site or dispensary and who is entitled to receive 40 percent or more of the proceeds from the marijuana processing site or dispensary as a part of lease payments or rent, any individual who owns, directly or indirectly, 10 percent or more of the ownership interests of a business entity that is a landlord of a processing site or dispensary and that is entitled to receive 40 percent or more of the proceeds from the marijuana processing site or dispensary as part of lease payments or rent, and any individual who the Authority finds, based on reasonably reliable information, exerts influence over the operation of the marijuana processing site or dispensary through a landlord-tenant relationship and receives a portion of the proceeds from that marijuana processing site or dispensary.

(h) Other forms of business organization: If the form of business entity is not expressly addressed in subsections (a) to

(g) of this section, the Authority will, in determining individuals who have a financial interest in the business entity, apply the portions of this definition applicable to the business entity that are most similar to the subject business entity, interpreting the terminology and concepts of this definition in the context of the subject business entity as necessary or appropriate.

(35) "Indoor production" for purposes of OAR 333-008-0580 means producing marijuana in any manner:

(a) Utilizing artificial lighting on mature marijuana plants; or

(b) Other than "outdoor production" as that is defined in this rule.

(36) "Limited access area" means:

(a) For a dispensary a building, room, or other contiguous area on a dispensary premises where a marijuana item is present but does not include the area where marijuana items are transferred to a patient or designated primary caregiver.

(b) For a processing site a building, room, or other contiguous area on a processing site premises where a marijuana item is present.

(37)(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.

(38) "Marijuana item" means marijuana, cannabinoid concentrates, cannabinoid extracts, medical cannabinoid products, and immature marijuana plants.

(39) "Marijuana processing site" or "processing site" means a marijuana processing site registered under ORS 475B.840 or a site for which an applicant has submitted an application for registration under ORS 475B.840.

(40) "Mature marijuana plant" means a marijuana plant that is not an immature marijuana plant.

(41)(a) "Medical cannabinoid product" means a cannabinoid edible and 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 dried leaves or flowers of marijuana.

(b) "Medical cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate by itself;

(C) A cannabinoid extract by itself; or

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

(42) "Medical marijuana dispensary" means a medical marijuana dispensary registered under ORS 475B.858 or a site for which an applicant has submitted an application for registration under ORS 475B.858.

(43) "Medical use of marijuana" means the production, processing, possession, delivery, or administration of marijuana, or use of paraphernalia used to administer marijuana to mitigate the symptoms or effects of a debilitating medical condition.

(44) "Minor" means an individual under the age of 18.

(45) "Oregon Health Plan (OHP)" means the medical assistance program administered by the Authority under ORS chapter 414.

(46) "OMMP" means the section within the Authority that administers the provisions of ORS 475B.785 to 475B.949, the applicable provisions of 475B.550 to 475B.590, 475B.600 to 475B.655, and the rules in OAR chapter 333, divisions 7 and 8.

(47) "Outdoor production" for purposes of OAR 333-008-0580 means producing marijuana:

(a) In an expanse of open or cleared ground open to the air; or

(b) In a greenhouse, hoop house or similar non-rigid structure that does not utilize any artificial lighting on mature marijuana plants, including but not limited to electrical lighting sources.

(48) "Parent or legal guardian" means the custodial parent or legal guardian with responsibility for health care decisions for the person under 18 years of age.

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

(50) "Person designated to produce marijuana by a registry identification cardholder" or "person designated to produce marijuana by a patient" mean a person designated to produce marijuana by a patient under ORS 475B.810 who produces marijuana for that patient at an address:

(a) Other than the address where the patient resides; or

(b) Where more than 12 mature marijuana plants are produced.

(51) "Person responsible for a marijuana grow site," or "PRMG" means any individual designated by a patient to produce marijuana for the patient, including a patient who identifies themself as a person responsible for the marijuana grow site, who has been registered as a PRMG by the Authority under OAR 333-008-0033.

(52) "Personal agreement" means a document, as described in ORS 475B.822 signed and dated by a patient, assigning a patient's right to possess seeds, immature marijuana plants and usable marijuana to a PRMG.

(53) "Point of sale" means a specific location within a point of sale area at which the transfer of a marijuana item occurs.

(54) "Point of sale area" means a secure area where a registered dispensary transfers a marijuana item to a patient or caregiver.

(55) "Premises" means a location registered by the Authority as a processing site or dispensary under these rules and includes all areas at the location that are used in the business operated at the location, including offices, kitchens, rest rooms and storerooms, including all public and private areas where individuals are permitted to be present.

(56) "Primary responsibility" as that term is used in relation to an attending physician means that the physician:

(a) Provides primary health care to the patient; or

(b) Provides medical specialty care and treatment to the patient as recognized by the American Board of Medical Specialties; or

(c) Is a consultant who has been asked to examine and treat the patient by the patient's primary care physician licensed under ORS chapter 677, the patient's physician assistant licensed under ORS chapter 677, or the patient's nurse practitioner licensed under ORS chapter 678; and

(d) Has reviewed a patient's medical records at the patient's request and has conducted a thorough physical examination of the patient, has provided or planned follow-up care, and has documented these activities in the patient's medical record.

(57) "Process" means the compounding or conversion of marijuana into medical cannabinoid products, cannabinoid concentrates or cannabinoid extracts.

(58) "Process lot" means:

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

(b) Any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract as defined in subsection (a) of this section.

(59) "Production" or "growing" means:

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

(b) Drying marijuana leaves or flowers.

(60) "Registry identification card" means a document issued by the Authority under ORS 475B.797 that identifies a person authorized to engage in the medical use of marijuana, and, if the person has a designated primary caregiver under ORS 475B.804, the person's designated primary caregiver.

(61) "Registry identification cardholder" means a person to whom a registry identification card has been issued under ORS 475B.797(5)(a) and has the same meaning as patient.

(62) "Remuneration" means compensation resulting from the employer-employee relationship, including wages, salaries, incentive pay, sick pay, compensatory pay, bonuses, commissions, stand-by pay, and tips.

(63) "Replacement card" means a new card issued in the event that:

(a) A patient's registry identification card, a designated primary caregiver's or a PRMG's identification card, or grow site registration card is lost or stolen; or

(b) A patient's designation of primary caregiver, PRMG or grow site has changed.

(64) "Residence" means the real property inhabited by a patient for a majority of a calendar year or, if a patient maintains multiple residences, real property inhabited by a patient for the greatest percentage of time within a calendar year.

(65) "Resident" means an individual who has primary domicile within this state.

(66) "Safe" means:

(a) A metal receptacle with a locking mechanism capable of storing all usable marijuana at a registered premises that:

(A) Is rendered immobile by being securely anchored to a permanent structure of the building; or

(B) Weighs more than 750 pounds.

(b) A vault; or

(c) A refrigerator or freezer capable of being locked for storing edibles or other finished products that require cold storage that:

(A) Is rendered immobile by being securely anchored to a permanent structure of the building; or

(B) Weighs more than 750 pounds; and

(C) If it has a glass that makes up part or all of the door or exterior walls, the glass is rated unbreakable.

(67) "Secondary school" means a learning institution containing any combination of grades 9 through 12 and includes those institutions that provide junior high schools which include 9th grade.

(68) "Secure area" means a room:

(a) With doors that are kept locked and closed at all times except when the doors are in use;

(b) Where access is only permitted as authorized in these rules; and

(c) Not visible from outside the room or within public view.

(69) "Supplemental Security Income (SSI)" means the monthly benefit assistance program administered by the federal government for persons who are age 65 or older, or blind, or disabled and who have limited income and financial resources.

(70) "These rules" means OAR 333-008-0010 to 333-008-0750.

(71) "THC" means tetrahydrocannabinol.

(72)(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 marijuana.

(73) "Vault" means an enclosed area that is constructed of steel-reinforced or block concrete and has a door that contains a multiple-position combination lock or the equivalent, a relocking device or equivalent, and a steel plate with a thickness of at least one-half inch.

(74) "Written documentation" means a statement signed and dated by the attending physician of a person diagnosed with a debilitating medical condition or copies of the person's relevant medical records, maintained in accordance with standard medical record practices.

(75) "Zoned for residential use" means the only primary use allowed outright in the designated zone is residential.

STATUTORY/OTHER AUTHORITY: ORS 475B.949

STATUTES/OTHER IMPLEMENTED: ORS 475B.785 — 475B.949

AMEND: 333-008-0638

RULE TITLE: Grow Site Administrators for CTS Tracking

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending rule language to state that in order to be approved as a grow site administrator the person would need to be in good standing with the program for the previous three years.

RULE TEXT:

(1) Designation of Grow Site Administrator for CTS.

(a) On and after May 31, 2018, a grow site that is subject to CTS tracking under OAR 333-008-0635(1) must have a designated grow site administrator.

(b) If a grow site that is subject to CTS tracking under OAR 333-008-0635(1) applied for a producer license with the Commission on or before January 1, 2018, and the Commission on or after August 17, 2018 declares the license application incomplete or proposes to deny a grow site's application for a producer license, a PRMG at the grow site must submit a request to be designated the grow site administrator to the Authority in a form and manner prescribed by the Authority, along with the required CTS non-refundable user fee, within 15 calendar days of the date of the Commission's action finding the application incomplete or proposing denial.

(c) If a patient submits an application listing a grow site and the new application makes the grow site subject to CTS tracking criteria under OAR 333-008-0635(1) the Authority will notify all PRMGs at the grow site that a grow site administrator must be designated. The PRMG designated as the grow site administrator has 15 calendar days from the date of the Authority's notice to submit a grow site administrator request to the Authority in a form and manner prescribed by the Authority, along with the CTS non-refundable user fee.

(2) If a grow site administrator request is not submitted to the Authority by the deadlines established in this rule the Authority may revoke the registration of each PRMG at the grow site location and revoke the grow site registration.

(3) If more than one grow site administrator request is received for the same grow site location, and the Authority approves a request, the Authority will not review any additional requests.

(4) The Authority shall review and act on grow site administrator requests in the order they are received.

(5) The Authority will approve a request to be designated the grow site administrator if:

(a) The request is complete;

(b) The PRMG is in good standing with the Authority and the Commission. For purposes of this section "in good standing" means the PRMG has not been subjected to discipline by the Authority or the Commission within the previous three years; and

(c) The PRMG requesting approval as the grow site administrator has authorized the Authority to provide the administrator's contact information to all other PRMGs registered at the grow site or who become registered at the grow site and all patients for whom a PRMG is producing marijuana at the grow site, upon approval.

(6) The Authority will notify the approved grow site administrator of the approval or denial and will notify the Commission of all approved grow site administrators so the Commission can begin the process of setting up the grow site's CTS account.

(7) Withdrawal of grow site administrator approval.

(a) If the approved grow site administrator fails to remain registered with the Authority, fails to remain in good standing with the Authority or the Commission, or if the administrator's registration has been suspended or revoked by the Authority, the Authority shall withdraw the administrator's approval. The Authority shall notify the administrator of the withdrawal and cite the reasons for the withdrawal, in writing. The Authority shall notify the Commission when a grow site administrator approval is withdrawn.

(b) If the Authority withdraws its approval of the administrator it shall notify all PRMGs at the grow site location that a new grow site administrator must be designated. The PRMG designated as the grow site administrator has 15 calendar days from the date of the Authority's notice to submit a grow site administrator request to the Authority in a form and manner prescribed by the Authority, along with the CTS non-refundable user fee, if applicable. The request for approval of a new grow site administrator shall be conducted in accordance with sections (5) and (6) of this rule.

(8) Change of grow site administrator.

(a) An approved grow site administrator may submit a notice of resignation in a form and manner prescribed by the Authority, that the administrator is resigning as the administrator. The administrator may, at the same time, request a replacement grow site administrator for the grow site location. The PRMG designated as the grow site administrator has 15 calendar days from the date of the Authority's

notice to submit a grow site administrator request to the Authority in a form and manner prescribed by the Authority, along with the CTS non-refundable user fee, if applicable.

The Authority will act on the new request in accordance with sections (5) and (6) of this rule.

(b) Any PRMG at a grow site location may submit a request to the Authority to change the approved grow site administrator, in a form and manner prescribed by the Authority.

(A) The request to change the grow site administrator must include the reasons for the requested change. The requestor must provide the approved grow site administrator a copy of the request.

(B) In addition to the request to change the approved grow site administrator, at least one PRMG at the grow site must submit a request to be approved as the grow site administrator to the Authority in a form and manner prescribed by the Authority, along with the required CTS non-refundable user fee, if needed.

(C) The Authority will notify the approved grow site administrator of the change request and allow the grow site administrator 15 calendar days to submit a written response to the change request, to the Authority.

(D) If the approved grow site administrator does not respond to the Authority or does not object to the change and if the PRMG requesting to become the new grow site administrator is qualified for approval under section (5) of this rule, the Authority will notify the administrator that the administrator's approval has been withdrawn and notify the new grow site administrator of the approval in accordance with section (6) of this rule. If the PRMG requesting to become the new grow site administrator is not qualified for approval under section (5) of this rule the request to change the approved grow site administrator will be denied.

(E) If the approved administrator responds to the change request in a timely manner and objects to the change the Authority will review all of the information submitted and determine if there is good cause to withdraw approval of the current administrator and approve a new administrator. For purposes of this rule "good cause" means the approved administrator is not complying with the rules of the Authority or the Commission with regard to CTS tracking or cannot for other legal reasons comply with such rules.

(i) If the Authority determines there is not good cause to withdraw approval of the approved grow site administrator the Authority shall notify the person who submitted the change request and the approved grow site administrator, in writing, of the Authority's decision and the reasons for the decision.

(ii) If the Authority determines there is good cause to withdraw approval of the currently approved grow site administrator the Authority shall notify the approved grow site administrator of the withdrawal in

writing and the reasons for the withdrawal, and notify the Commission. The request for approval of a new grow site administrator shall be conducted in accordance with sections (5) and (6) of this rule.

(c) The Authority may, but is not required, to accept a grow site administrator's notice of resignation. The resignation is not effective until the authority informs the grow site administrator, in writing, that the resignation has been accepted.

(9) No PRMG at a grow site that is subject to OAR 333-008-0635 may transfer any seeds, immature medical plants or usable medical marijuana unless the grow site has an approved grow site administrator and an active CTS account.

(10) The CTS non-refundable user fee must be paid by the approved grow site administrator on an annual basis. A request to be designated the grow site administrator under section (8) of this rule must be accompanied by a CTS nonrefundable user fee if the request is made within 45 days of the due date for the annual CTS non-refundable user fee.

STATUTORY/OTHER AUTHORITY: ORS 475B.895, 475B.949

STATUTES/OTHER IMPLEMENTED: ORS 475B.895

AMEND: 333-008-1610

RULE TITLE: Medical Marijuana Processors: Definitions

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amend definitions to be consistent with definitions found in OLCC rules.

RULE TEXT:

For purposes of OAR 333-008-1600 to 333-008-2200:

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

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

(3) "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.

(4) "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.

(5) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.

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

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

(8) "Person responsible for the marijuana processing site" or "PRP" means an individual who is directly involved in the day-to-day operation of a processing site and is identified as a PRP on an application.

(9) "Primary PRP" means a PRP designated by the owner of the processing site as the primary point of contact for the Authority and who is authorized to receive any and all communications and legal notices from the Authority.

(10) "Processing site representative" means an owner, director, officer, PRP, manager, employee, agent or other representative of a registered processing site, to the extent that the person acts in a representative capacity.

(11) "Processing site registrant" means:

(a) An individual who owns a registered processing site or if a business entity owns the registered processing site, each individual who has a financial interest in the registered processing site; and

(b) Any PRP.

(12) "These rules" means OAR 333-008-1600 to 333-008-2200.

STATUTORY/OTHER AUTHORITY: ORS 475B.840

STATUTES/OTHER IMPLEMENTED: ORS 475B.840

AMEND: 333-064-0025

RULE TITLE: Definitions

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Amending definitions to match definitions found in OAR 333-007-0310.

RULE TEXT:

As used in these rules, unless the context indicates otherwise:

(1) "Accrediting body" means the official accrediting authority for the Oregon Environmental Laboratory Accreditation Program comprised of the Administrator of the Oregon State Public Health Laboratory or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory Administrator of the Department of Agriculture or designee.

(2) "Air" as a matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.

(3) "Authority" means the Oregon Health Authority.

(4) "Biological tissue" as a matrix means samples of biological tissue, excluding those of human origin.

(5) "Cannabis sampling" means an activity related to obtaining a representative sample of a marijuana item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.

(6) "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.

(7) "Clean Air Act (CAA)" means the enabling legislation, 42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399, that empowers the EPA to promulgate air quality standards, monitor and enforce them.

(8) "Clean Water Act (CWA)" means the enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816 that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.

(9) "Drinking water" as a matrix means samples of presumed potable water and source water, which are analyzed for possible contaminants under the guidance of the Safe Drinking Water Act.

(10) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.

(11) "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.

(12) "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.

(13) "Laboratory" means a fixed location or mobile facility that collects or analyzes samples in a controlled and scientific manner with the appropriate equipment and instruments required by accredited sampling and testing methods.

(14) "Marijuana item" has the meaning given that term in ORS 475B.550.

(15) "Mobile Category 1 Laboratory" means any facility, deployed for no more than six consecutive months and no more than six months during a calendar year, that:

(a) Analyzes samples utilizing the staff and equipment from the parent fixed laboratory;

(b) Operates under the quality system of its parent fixed laboratory;

(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and

(d) May operate under the fixed laboratory's accreditation.

(16) "Mobile Category 2 Laboratory" means any facility that:

(a) Analyzes samples;

(b) Operates under its own quality system;

(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and

(d) Issues the final reports or is a mobile laboratory operating with a fixed laboratory's quality system, but is deployed for more than six consecutive months or more than six months in a calendar year.

(17) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.

(18) "NELAP approved accrediting body" means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the TNI Standards.

(19) "Non-potable water" as a matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.

(20) "On-site assessment" means an on-site visit to the laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards.

(21) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.

(22) "Primary accreditation" means accreditation by a NELAP approved accrediting body based on a laboratory's compliance to TNI Standards after a review of the laboratory's application, quality manual, PT results and on-site assessment results as described in the TNI Standards.

(23) "Proficiency testing (PT)" means the analysis of samples obtained from providers that meet the TNI standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.

(24) "Public water system" means a water system as defined in OAR 333-061-0010.

(25) "Quality Manual (QM)" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.

(26) "Resource Conservation and Recovery Act (RCRA)" means the enabling legislation, 42 U.S.C. section 6901 et seq. (1976), that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.

(27) "Safe Drinking Water Act (SDWA)" means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.

(28) "Scheduled proficiency testing" means a single complete sequence of circulation and scoring of proficiency testing sample for a participant in a proficiency test program with predefined opening and closing dates for any participant.

(29) "Secondary accreditation" means the recognition by reciprocity for the fields of accreditation, methods and analytes for which the laboratory holds current primary accreditation by another NELAP approved accrediting body.

(30) "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act. Cannabinoid products and concentrates or extracts as defined in ORS 475B.550 shall be included in this matrix as solids.

(31) "Supplemental proficiency testing" means a PT study that may be from a lot previously released by a PT provider but that does not have a pre-determined opening date and closing date but the closing date cannot exceed 45 days from the opening date.

(32) "TNI" means the NELAC Institute. TNI is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

(33) "TNI Standards" means the adopted TNI Standards (© 2009 The NELAC Institute), which are documents describing the elements of laboratory accreditation that was developed and established by the consensus principles of TNI and meets the approval requirements of TNI procedures and policies.

(34) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0120.

(35) "Third party assessor" means an ORELAP approved assessor who has a current contract with the Oregon Health Authority to perform on-site assessments of laboratories for ORELAP and is not employed by the state agencies comprising ORELAP's accrediting body.

(36) "United States Environmental Protection Agency (EPA)" means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (that is air, water, and land) upon which human life depends.

[Publications: Publications referenced are available from the agency.]

STATUTORY/OTHER AUTHORITY: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150(1), 448.280(1)(b), (2)

STATUTES/OTHER IMPLEMENTED: ORS 438.605, 438.610, 438.615, 438.620, 448.280(1)(b), (2)

AMEND: 333-064-0100

RULE TITLE: Marijuana Item Sampling Procedures and Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Clarifying language for sampling of marijuana items in rule and ORELAP's Protocol for Collecting Samples of Finished Cannabinoid Concentrates, Extracts and Products.

RULE TEXT:

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) Sampling.

(a) A laboratory must have and follow marijuana item sampling policies and procedures, accredited by ORELAP, that:

(A) Ensure sampling will result in a sample that is representative of the batch being sampled.

(B) Require sampling and laboratory personnel to document and collect any information necessary for compliance with these rules, OAR chapter 333, division 7, and any applicable TNI standards.

(C) Require chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8.

(D) Are appropriate to the matrix being sampled.

(E) Are consistent with OAR 333-007-0360 and 333-007-0370 and the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:

(i) Usable Marijuana: ORELAP-SOP-001 Rev 3.1; and

(ii) Concentrates, Extracts, and Products: ORELAP-SOP-002 Rev 3.3. [Sampling protocols may be found on the ORELAP and Cannabis Testing webpage, public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx].

(F) Ensure that only the finished cannabinoid concentrate, extract or product is sampled if testing on the finished cannabinoid concentrate, extract or product is required under OAR 333-007-0330 and OAR 333-007-0340.

(G) Contain training and education requirements for sampling personnel.

(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken.

(c) Laboratory personnel that perform sampling must:

(A) Comply with the laboratory's accredited sampling policies and procedures.

(B) After taking samples:

(i) Document the samples in accordance with subsection (2)(e) of this rule; and

(ii) If sampling for a licensee or a registrant required to comply with CTS tracking under ORS 475B.895, record the sampling and transfer information in the Commission's seed to sale system, as required by the Authority and the Commission; and

(C) Take care while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.

(D) Take sample increments that are representative of the batch being sampled.

(d) 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.

(e) A laboratory must comply with any recording requirements for samples and sample increments in the accredited policies and procedures and at a minimum:

(A) Record the location of each sample and sample increment taken.

(B) Assign a field identification number for each sample, sample increment and field duplicate that have an unequivocal link to the laboratory analysis identification.

(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.

(E) Place the laboratory identification code as a durable mark on each sample container.

(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.

(f) Combining sample increments.

(A) Sample increments collected from the same batch of usable marijuana must be combined into a single sample by a laboratory prior to testing. Sample increments from a batch of a cannabinoid concentrate, extract or product may be combined into a single sample by a laboratory prior to testing if the cannabinoid concentrate, extract or product has a certified control study.

(B) Sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360.

(C) Field duplicates may not be combined with the primary samples.

(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.

(4) Calculating total THC and total CBD.

(a) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:

M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THCA.

(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:

M total CBD = M CBD + 0.877 x M CBDA.

(c) Each test report must include the total THC and total CBD.

(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

P total THC(dry) = P total THC(wet) / [1-(P moisture/100)]

P total CBD(dry) = P total CBD(wet) / [1-(P moisture/100)]

(6) Calculating RPD and RSD.

(a) A laboratory must use the following calculation for determining RPD:

Relative Percent Difference

%RPD=/(sample—duplicate)/(sample+duplicate)/2 x 100

(b) A laboratory must use the following calculation for determining RSD:

Standard Deviation

S= i=1n(xi—x)2(n—1)

Relative Standard Deviation

%RSD= Sx x 100

(c) For purposes of this section:

(A) S = standard deviation.

(B) n = total number of values.

(C) xi = each individual value used to calculate mean.

(D) x = mean of n values.

(d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.

(7) Tentative Identification of Compounds (TIC).

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.

(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).

(c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.

(d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.

(A) The top five matches over 90 percent must be reported by the lab

(B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.

(8) A laboratory must provide:

(a) Any pesticide test result to the Department of Agriculture upon that agency's request.

(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.

(9) A laboratory performing tests for a licensee or a registrant required to use CTS under ORS 475B.895 must enter any information required by the Commission or the Authority in CTS. (10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.

(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-0500 and these rules based on the state's needs.

(12) A laboratory must be able to demonstrate that its LOQ is below any action level established in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 and 4.

(13) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant or licensee may use methods not approved by the Authority but the laboratory may not identify those test results as accredited results.

STATUTORY/OTHER AUTHORITY: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555.

STATUTES/OTHER IMPLEMENTED: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555

Oregon

Environmental Laboratory Accreditation Program

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Department of Environmental Quality, Laboratory and Environmental Assessment Program

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Protocol for Collecting Samples of Usable Marijuana

ORELAP-SOP-001 Rev. 3.1

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06/23/17

Date

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Laboratory Manager

Introduction and Scope

Laboratory analysis relies on sampling to characterize a larger batch. Hence, the process of taking a representative sample is the beginning of laboratory analysis.

For the purposes of this document, a batch is defined as "a definite quantity of usable marijuana from a harvest lot" identified by a batch number or other unique identifier, every portion of which is assumed to be uniform, within permitted tolerances." Oregon Administrative Rule (OAR) 333-007-0320 describes the testing requirements for Usable Marijuana. To reliably provide the laboratory with a representative sample, standard sampling methods must be applied with consistency. In addition, sampling practices and devices must be "correct" for the matrix. This controls variable factors in the sampling procedure, which may introduce error or bias resulting in a non-representative sample. A certain amount of random error is intrinsic to all measurements and may be minimized by close adherence to well documented standard procedures.

Production error is the responsibility of the producer of the Usable Marijuana product. Sampling error must be controlled in order to obtain a representative sample of the defined batch. This is accomplished by maintaining the sample identity within the defined batch, prevention of contamination of the sample, and consistent use of standard sampling methods and equipment. If proper controls are in place for sample collection, the laboratory report produced from the testing of the sample should reflect the quality of the batch within recognized tolerances at the time of sampling.

This protocol will focus on standard and correct sampling practices and sampling devices. The laboratory must meet the client needs for uncertainty, risk, and liability in the sampling contract. It is strongly recommended that the laboratories encourage clients to mitigate risk of uncertainty in representativeness by increasing the number of individually analyzed samples for each test. The specifications in the contract are met by creating a site specific sampling plan or process specific sampling plan that uses statistical design for each project to meet the confidence interval requested

by the client. Unless the contract states otherwise, a laboratory need only collect the minimum number of samples required in OAR 333-007-0360 and as recommended in this protocol.

Prior to any sample increments being taken a sampler must receive a test order form as required by OAR 333-007-0315.

Incremental and Representative Sampling Design

Accurate and thorough recordkeeping is another essential aspect of the sampling procedure to connect the batch to the sample increments or composite samples and, eventually, to the laboratory report. At a minimum, a sampling report shall accompany the sample, which shows the harvest and batch information including producer, product type, batch size, batch number, name and address of where sampled, the number of containers sampled, number of sample increments collected, the sampler's name, and the date sampled. It is always necessary for the sampler to keep a copy of the sampling report. A thorough record of the sample is best maintained on a form specifically designed for that purpose.

Representative Sampling

When sampling a batch, the sampler shall check for any signs of non-uniformity. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers. During sampling, the sampler shall look for differences in the usable marijuana being sampled such as color, shape, size, and treatment. By definition, the batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the batch and that any sample drawn may not be representative for testing. The sampler shall note these anomalies in the sample collection report.

General procedural guidelines that apply to all sampling include:

1. Gaining access to the entire batch;

2. Use of appropriate sampling equipment and consistently following procedures;

3. Taking equal portions for each sample increment;

4. Randomly or systematically taking sample increments throughout the batch;

5. Obtaining a minimum number of sample increments, which will be based on batch size; and

6. Recording all observations and procedures used while collecting the sample increments on an appropriate sampling form.

Random Sampling

As specified in the sampling plan, sample increments should be randomly selected from different locations within a container or set of containers. Laboratories must develop procedures describing how to:

1. Assign location numbers within containers;

2. Use a random number generator to determine which location to sample; and

3. Document where each sample increment was sampled and the volume collected from each increment.

Assign divisions based on the type of container in the site specific sampling plan. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers use existing or arbitrary order of containers to assign numbers to the total of "divisions multiplied by total number of containers" (divisions x # containers = total number of random increments) and record in the sampling report.

The laboratory must have details in its SOP or Sampling Plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

Procedures for Sampling Usable Marijuana

Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the Usable Marijuana is being kept, as this will determine the sampling plan. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for Usable Marijuana are in OAR 333-007-0320. The requirements for sampling and sample size are in OAR 333-007-0360. Per Authority or Commission request or client request, other analyses may require sampling and must be part of the planning process.

In cases where Usable Marijuana will be sold or transferred to a processor or processing site, analysis may occur prior to the drying and curing steps. To ensure representativeness, the sampling plan must be designed such that each flower bud in the batch has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required, but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 15 lbs**.

Equipment and Supplies

• Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools

• Tongs

• Corers

• Teri-wipes, or equivalent

• Field balance (Capable of 0.01 g measurements)

• Calibrated Verification Weights appropriate to verify accuracy of field balance

• Cleaning supplies - solvent, bleach, 70% Ethanol

• Gloves (powder-free, nitrile, sterile)

• Mylar Bags (For final sample transport and storage) And/Or

• Amber Glass jars (For final sample transport and storage)

Records and Documentation

Laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

• The SOP shall be readily accessible to all pertinent personnel.

• The SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.

• The sampling SOP shall use these protocols as minimum requirements and must include additional detail specific to laboratory procedures. Any changes, including use of a selected option, shall be documented and included on the sampling form. In cases where the published method has been modified or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.

• All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-007-0310.

The ORELAP accredited laboratory shall maintain sampling plans (2009 TNI ELV1M2 5.7). These documents must be made available at their location of use. Sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch. Standardized Sampling Plans

can be included in the SOP however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.

Sampling Records/Field Data

In addition to collecting the sample, a sampling report form must be made for the batch sampled and must include any observations made while taking the sample. This documentation shall include the following information:

• Name and address of producer including licensee or registrant number;

• Product type;

• Total mass of batch;

• Unique laboratory batch ID#,METRC batch ID #, and/or OHA batch ID#; as designated

• Total container number;

• Number of sample increments;

• Number of containers sampled;

• Number of sample containers collected;

• Total mass sampled;

• Sampling plan ID and revision date;

• Sampling Procedure ID and revision date;

• Description of equipment used;

• Place where sampled;

• Date sampled;

• ORELAP Laboratory Identification number;

• Sampler's identification and/or signature;

• Name of responsible party for the batch and transport information;

• Receiving laboratory and types of tests required or requested.

While procuring the sample, in the absence of METRC procedures that contain the below information, the laboratory must create a Chain of Custody form with the following information:

• Sampler's name

• Lab License Number

• Sample Identification (Lab ID number) if assigned before arrival at laboratory

• Sampling Date/Time

• Mass and Location of increment samples

• Final Mass of composite sample

• Custody transfer signatures

• Custody Transfer Dates/Times

If any of the above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space. All sampling report forms must be signed by the sampler.

Sampling a Batch of Usable Marijuana

1. Locate the batch to be sampled.

2. Review the container label information for harvest lot number, producer, and other pertinent information. Each harvest lot must be separated into batches of 15 lbs. or less and must be

Protocol for Collecting Samples of Usable Marijuana assigned a unique batch number by the grower. Do not sample if a unique batch number is not available. 3. Determine the number of containers in the batch and the batch size. Visually verify the batch

3. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container. Do not sample if the batch size is unavailable or exceeds 15 lbs. for a container.

4. Determine the number of containers from which sample increments must be collected (Appendix 2).

5. Select the appropriate sampling tool to ensure that it reaches all portions of the container.

6. Collection instruments must be clean prior to use to prevent cross-contamination of sample increments. Sampling tools which appear to be dirty or otherwise compromised shall not be used. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. Decontamination waste must be collected and properly disposed of if not used for analysis.

Note: Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler is required to bring enough sets of sampling equipment to use a new set at each facility visited. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures. Where aseptic technique is required, apply the FDA Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6) when taking samples:

7. Visually inspect each test sample increment to assess uniformity;

8. If non-uniformity is identified, record observation in the sampling report. It is expected with Usable Marijuana to have variable sizes of flowers. When drawing sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected.

9. Combine all sample increments to form the composite sample.

10. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.

11. Seal and label the composite sample with the following minimum requirements:

• Laboratory license number

• Unique identifier for sampling event

• Sampling date and name of sampler

• Producer's license or registration number

• Harvest lot and batch numbers

• Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12 point font. 12. Apply a custody seal to the sample container in a manner which prevents the product from

12. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the laboratory sample identification number.

13. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in 2009 TNI EL V1M2 5.8.1 through 5.8.7.

14. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.

15. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational marijuana or record in the laboratory's records the registrant number for tracking medicinal marijuana.

Sample Preservation, Handling and Storage

Preparation of the Composite Sample

1. Transport the sample to the analysis laboratory following OLCC license regulation for transport. Note: The existing regulation does not permit shipping in any form such as USPS or FedEx.

2. The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.

3. Submit the composite sample to the laboratory in its entirety.

4. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report. Containers for sample transport must be designed to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling is a glass, amber jar with a PTFE-lined lid or a Mylar bag. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.

Forwarding Samples to the Primary and/or Re-testing Laboratory

1. Forward the composite sample to the laboratory or other designated location using packaging appropriate for secure transport.

2. Protect the sample from moisture and temperature extremes.

3. Include all documentation with the sample.

4. Forward the sample by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody is accounted for to protect its integrity.

Quality Assurance/Quality Control

Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments to compensate for normal batch heterogeneity. It is recommended that a minimum of ten (10) sample increments be taken for the sample to be considered a representative decision unit for Usable Marijuana.

The sampler must be prepared to collect adequate sample mass for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.

Field QC

Field sampling equipment shall be certified clean prior to use by the laboratory. Cleaning techniques will vary depending upon the desired analysis. In general, sampling equipment must be sterile for microbiology samples and clean for chemistry samples. The laboratory shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.

Field Duplicates

Field Duplicates are recommended for any Usable Marijuana sampling event, but not required. The Field Duplicate must be collected using the same procedure and contain the same number of sample increments as the Primary Sample. The lab must have documentation of the client request for a Field Duplicate with any client specified Quality objectives and precision limits must meet the client's need.

Equipment Blanks

Equipment rinse blank samples provide a QC check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning.

The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.

The Equipment Blank must pass the required analysis at <LOQ for cleaning validation.

If the Equipment Blank is collected at the sampling event, the lab must have detail in the sampling plan or procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

Demonstration of Capability

Prior to acceptance and institution of any method for which data will be reported, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method, and, 2) when the method has not been performed by the laboratory or sampler within a 12-month period.

This procedure shall employ one of the following approaches to demonstrating capability:

1. Comparison of replicate samples within a defined Relative Standard Deviation (%RSD) [1].

[1] Standard Methods 20th Edition; 1020 B Quality Control, 11. QC Calculations, a. Initial Calibration.

2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD.

Thereafter, ongoing continuing demonstration of capability (CDOC) as per the quality control requirements referenced in the method is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

Sampler Qualifications

Basic qualifications for samplers of Usable Marijuana are:

• Physically able to perform the duties of a sampler;

• No conflict of interest;

• Must be employed by an ORELAP accredited laboratory

• Pass initial and ongoing demonstrations of capability;

• Licensed to transport the required quantity of Usable Marijuana items

Education and training for samplers:

• Initial classroom training: 8-hours of training, including principles, procedures, and policies of sampling; Initial Training must be performed by an Instructor that has demonstrated competency in performing and instructing on the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.

• Field or on-the-job training: 8-hours of training on various sampling techniques;

• Continuing education: 8-hours of periodic refresher training annually.

Field Audits

The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits must be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.

When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.

Auditing Checks

1. Using audit checklists:

a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol;

b. Observe the sampler conducting sampling procedures;

c. Have the auditor and sampler collect samples from the same harvest lot for evaluation and comparison of results.

2. Record any deficiencies and initiate corrective action.

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http://www.nelac-institute.org/content/CSDP/standards.php

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Oregon Administrative Rules, *General Requirements Applicable to all Marijuana Licensees,* Chapter 845, Division 25.

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Appendix 1 - Definitions

** If there are any inconsistencies between the definitions below and the definitions in OAR 333, Divisions 7 and 64, the definitions in the rules take precedence.

Authority means Oregon Health Authority

Batch means a quantity of Usable Marijuana from a harvest lot.

Chain of Custody means the chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample. (Sample tracking document)

Commission means the Oregon Liquor Control Commission.

Composite sample means a sample containing all sample increments taken from a batch.

Container means a sealed, hard or soft bodied receptacle in which a marijuana item is placed or a physical division of a marijuana batch for random and representative sampling.

Decision Unit (DU) means the material from which the primary sample(s) is collected and to which the inference(s) is made.

Equipment Blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate cleaning procedure or between sampling batches to demonstrate lack of contamination.

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.

Fundamental Sampling Error (FSE) means the results from compositional heterogeneity, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

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

Heterogeneity means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

Homogeneous means uniform in composition within recognized tolerances.

Label means a tag or other device attached to or written, stamped, or printed on any container or accompanying any batch in bulk stating all required batch information.

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 ORS475B.560.

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include industrial hemp, as defined in ORS 571.300.

Marijuana item means marijuana, Usable Marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

ORELAP means the Oregon Environmental Laboratory Accreditation Program.

Primary Sample means a sample composed of sample increments and tested for the required analysis methods.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.420.

Relative Percent Difference means comparing two quantities while taking into account the "sizes" of the things being compared. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

Relative standard deviation means the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

Standard Deviation

Relative Standard Deviation

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

B = mean of n values.

Registrant means a person registered with the Authority under ORS475B.420, 475B.435, or ORS 475B.450.

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.

Representative Sample means a sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

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

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..

Sample Quality Criteria (SQC) means a series of statements that clarify program technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed means secured to provide authenticity or integrity.

Usable Marijuana means the dried and cured leaves and flowers of marijuana. Usable Marijuana does not include the seeds, stalks and roots of marijuana or waste material that is a by-product of producing or processing marijuana.

Appendix 2 - Recommended Sampling Guidelines

Sample size

Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required, but shall in no case be less than 0.5% of the weight of the batch. Per OAR 333-007-0350, the maximum batch size is 15 lbs.

The required sample size for a given batch size based on OAR 333-007-0360 varies depending upon the size of the batch (Table 1).

Table 1 - Sample size requirements based on size of batch.

Batch size	Required sample size		
	Pounds (lbs)	Ounces (oz)	Grams (g)
≤1 lbs	0.005	0.08	2.3
1.01 ≤2 lbs	0.010	0.16	4.5
2.01 ≤3 lbs	0.015	0.24	6.8
3.01 ≤4 lbs	0.020	0.32	9.1
4.01 ≤5 lbs	0.025	0.40	11.3
5.01 ≤6 lbs	0.030	0.48	13.6
6.01 ≤7 lbs	0.035	0.56	15.9
7.01 ≤8 lbs	0.040	0.64	18.1
8.01 ≤9 lbs	0.045	0.72	20.4
9.01 ≤10 lbs	0.050	0.80	22.7
10.01 ≤11 lbs	0.055	0.88	25.0
11.01 ≤12 lbs	0.060	0.96	27.3
12.01 ≤13 lbs	0.065	1.04	29.6
13.01 ≤14 lbs	0.070	1.12	31.9
14.01 ≤15 lbs	0.075	1.20	34.2

Sampling a batch

1. When collecting a primary sample from a batch, a minimum of ten (10) sample increments shall be collected. Collect the sample increments by following different paths through the batch container or by taking the sample increments systematically at well-separated points along a heptagonal pattern.

2. As the batch increases in size, it is necessary to collect additional sample increments to make up the primary sample (Table 2).

Table 2 - Minimum number of sample increments for the primary sample based on batch size.

Size of batch (lbs)	≤ 2	≤ 4	≤ 6	≤ 8	≤ 10
No. of increments	7	7	8	8	9
Size of batch (lbs)	≤ 12	≤ 14	≤ 15		
No. of increments	9	10	10		

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Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts and Products

ORELAP-SO P-002 Rev 3.3

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Acknowledgements

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Introduction and Scope

Laboratory analysis relies on sampling to characterize a larger batch. Hence, the process of collecting a representative sample is the beginning of the analytical process.

For the purposes of this document, a batch is defined as "a quantity of cannabinoid concentrate, extract, or cannabinoid product from a process lot" identified by a batch number or other unique

identifier. The testing requirements for cannabinoid concentrates, extracts and products are in Oregon Administrative Rules (OAR) 333-007-0330 to 333-007-0345.

To reliably provide the laboratory with a representative sample, standard sampling methods must be applied with consistency. In addition, sampling practices and devices must be "correct" for the matrix. This controls variable factors in the sampling procedure, which may introduce error or bias resulting in a non-representative sample. A certain amount of random error is intrinsic to all measurements and may be minimized by close adherence to well documented standard procedures.

Manufacturing error is the responsibility of the processor of the *Cannabis* product (concentrate, extract or product). Sampling error must be controlled in order to obtain a representative sample of the defined batch. This is accomplished by maintaining the sample identity within the defined batch, prevention of contamination of the sample, and consistent use of standard sampling methods and equipment. If proper controls are in place for sample collection, the laboratory report produced from the testing of the sample should reflect the quality of the batch within recognized tolerances at the time of sampling.

This protocol will focus on standard and correct sampling practices and sampling devices. The laboratory must meet the client needs for uncertainty, risk, and liability in the sampling contract. It is strongly recommended that the laboratories encourage clients to mitigate risk of uncertainty in representativeness by increasing the number of individually analyzed sample increments for each test. The specifications in the contract are met by creating a site specific sampling plan or process specific sampling plan that uses statistical design for each project to meet the confidence interval requested by the client. Unless the contract states otherwise, a laboratory need only collect the minimum number of sample increments required in OAR 333-007-0360, Exhibit B. Sample increments taken for a control study may not be combined.

After a control study is performed and certified by either the Authority or the Commission the laboratory can collect sample increments for a Primary Sample and a Field Duplicate Sample for ongoing validation of the control study:

• For cannabinoid concentrates and extracts, in accordance with OAR 333-007-0360(2)(c), Exhibit B, Table 7.

• For cannabinoid products, in accordance with OAR 333-007-0360(2)(d).

Prior to any sample increments being taken a sampler must receive a test order form as required by OAR 333-007-0315.

Incremental and Representative Sampling design

Accurate and thorough recordkeeping is another essential aspect of the sampling procedure to connect the batch to the sample and, eventually, the laboratory report. At a minimum, a site specific

or process specific sampling plan and a project specific sampling report should accompany the sample, which shows the sample information including product type, batch size, process lot and batch numbers, name and address of where sampled, the number of containers sampled, number of sample increments collected, the sampler's name, and the date sampled. Additional information may include the origin of the batch, production date, and other information needed for choosing sample increments. It is always necessary for the sampler to keep a copy of the sampling report. A thorough record of the sampling is best maintained on a form specifically designed for that purpose. In your sampling plan, the correct sample for analysis would be the sample that has the mean analyte concentration representative in the volume of sample increments needed for analysis. The sample may be a composite sample made up of sample increments randomly selected over a containerized cannabis concentrates, and extracts and products, if permitted under OAR 333-007-0360 and 333-007-0440.

Equipment and Supplies

The minimum equipment and supplies are listed in this protocol, however, lab procedures and sampling plans should have all equipment (sampling devices) necessary to take a consistent representative sample. The lab must also have procedures on cleaning the equipment or dedicated sampling disposal devices. The cleaning procedures must effectively eliminate carryover by removing any analyte of interest regardless of concentration of the analyte. This cleaning procedure must be validated initially and validated at any time the procedure, materials, or analyte of interest change, or there is evidence of contamination in samples.

Sampling equipment such as spoons, spatulas, forceps, syringe or transfer pipettes, or other matrix specific tools:

• Gloves (powder-free, nitrile, sterile)

• Sodium Hypochlorite (bleach) - for surface cleaning sampling tools for microbiology

• 70% Isopropyl alcohol - for surface cleaning sampling tools for pesticides and potency

• Teri-wipes, or equivalent

• Amber Glass containers

• Field balance (Capable of 0.01 g measurements)

• Calibrated Verification Weights appropriate to verify field balance Chain of Custody

• Custody Seals

• Sample Labels

• Sample Cooler/Ice (if thermal preservation required)

• Permanent Ink Pen

• Equipment Logbook (if balance used in field)

Procedures for Sampling Concentrate and Extract Products.

Planning

Prior to initiating a sampling event, a written sampling plan will be generated detailing the requirements and project. A sampling plan will detail sampling event(s) with specific specifications for the sampling event(s). The sampling plan should be as complete as possible before arriving on the sample site included such information as sampling devices and number of sample increments and size. If the sampling plan is a repeat event, based on a contract with a client, there should be a project plan with the information that will stay consistent.

For the sampling plan, whether with client-provided information or site information, the sampler shall survey the site and sampling locations to identify the matrix type and storage conditions of defined batch to be sampled. The sampling plan should identify, at a minimum, the quantity of sample increments to be collected, sample increment size, the sampling locations, the analysis to be performed, the sampling methodology required, and any other pertinent information regarding the sampling event. The sampling plan and any other supporting documents (i.e. SOP, protocols, forms, maps, etc.) must be readily available to the sampler at time of sampling event.

The sampling plan shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the representativeness of the sample(s) collected. Factors such as storage, environmental conditions, heterogeneity of the batch or sample, all must be considered and addressed in the sampling plan. Any deviation from the standard sampling process, or addition to the sampling plan must be documented in detail and shall be included in the final report.

All sampling must be performed by qualified personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and 333-064-0100.

Cannabinoid concentrates and extracts must be tested in accordance with OAR 333-007-0330. Cannabinoid products must be tested in accordance with OAR 333-007-0340. Per Authority or Commission request, or client request, additional analyses may be required, and will be specified by the laboratory in the written sampling plan. The sampling plan shall address representativeness of the samples collected; the sampling locations must be selected at random, and designed so that the samples collected reflect the total composition of the product. The sampling plan will address volume of sample to be collected from each sampling location. This specification will ensure that adequate

sample volume is collected for the analyses required, including all required quality control samples as well as any potential confirmation analysis.

Representative sampling

Data is only useful to the degree which the sample(s) collected represent the batch being analyzed. Based on client specifications and/or regulatory requirements, the sampler should identify sampling location(s) that represent the batch sufficiently to meet data quality objectives.

When sampling a batch the sampler should check for any signs of non-uniformity or anomalies that may result in deviation from sampling plan or may affect sample collection/analytical results. Examples of potential indicators may be different types, or sizes of containers, variations in marks and labels, or mixed batch numbers. Discrepancies shall be noted in the field record. During sampling, the sampler should look for differences in the *Cannabis* products being sampled such as size, color, matrix variability and treatment. The batch must be uniform for all factors identified in the sampling plan; product variations observed may indicate a lack of uniformity and sample collected may not be representative of the batch. The sampler must record these observations of the anomalies, and any preventative measures taken in the sample report .

General guidelines that apply to all sampling include:

• Use appropriate sampling equipment or devices, and thoroughly clean to prevent contamination;

• Follow all applicable procedures and the sampling plan;

• Taking equal increments as specified in the sampling plan to form each primary sample and duplicate or individual sample as required;

• Randomly or systematically take increments throughout the batch to create primary composite sample;

• Obtaining a minimum number of samples, as specified in the sampling plan;

• Recording all observations and procedures used while collecting the sample increments in an appropriate sampling record containing at a minimum the components described in the "Sampling Records/Field Data" section of this protocol. Any exceptions to these guidelines or deviations from the sampling plan must be noted in the field record. If a representative sample cannot be collected, the appropriate authority (client or regulatory) should be contacted immediately or the sample should be clearly identified as "for informational purposes only". Should the representativeness be in question, the sample increments should be collected and all pertinent data and observations, including those which may validate or invalidate the representativeness, shall be documented and submitted with the sampling record.

Random sampling

As specified in the sampling plan, sample increments should be randomly selected from different locations within a container or set of containers. Laboratories must develop procedures describing how to: 1) assign location numbers within containers; 2) use a random number generator to determine which location to sample; and 3) document where each s a m p l e increment was sampled and the volume or mass collected from each sample increment.

Assign divisions based on the type of container in the site specific sampling plan. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers, use existing or arbitrary order of containers to assign numbers to the total of "divisions multiplied by total number of containers" (divisions x # containers = total number of random sample increments) and record in the sampling report.

The laboratory must have details in their SOP or Sampling Plan, from appropriate industry reference where possible, on how they will achieve random sampling in unclear decision unit.

Records and Documentation

Laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

The SOP shall be readily accessible to all pertinent personnel.

The SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.

The sampling SOP shall use these protocols as minimum requirements and must include additional detail specific to laboratory procedures. Any changes, including use of a selected option, shall be documented and included on the sampling form. In cases where the published method has been modified or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.

The laboratory shall have SOP's for each sampling method.

All documents shall be controlled and retained in accordance with the TNI standard.

The laboratory needs to keep thorough records of each part of the process. The sampling plan, the sampling record, and chain of custody are required for each batch. If there is a quality assurance project plan for the client, the sampling plan can be abbreviated to include the client and lab information and any variation or modification that occurred in the particular sampling event.

Site Specific or Process Specific Sampling Plan/Project Plan/Request for Analysis

The laboratory shall maintain site and/or project specific sampling plans (2009 TNI EL V1M2 5.7). These documents must be made available at their location of use. Sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch. Standardized Sampling Plans can be included in the SOP, however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.

In some cases, especially when an on-going project plan is in place, the lab may wish to combine the sampling plan and sampling record. If this is the case, as much information about the site specific plan should be collected before sampling and there must be enough room on the record to record any deviations from the plan; including but not limited to number and orientation of containers to be sampled, mass, environmental conditions and any other factors that cannot be determined before arriving on-site. It must be clear on the combined sampling plan/record which information was recorded during planning and which information was recorded on-site with signatures of any applicable personnel.

As part of the planning process, the laboratory must receive a manifest or Request for Analysis from the client regarding the specific batch to be sampled (even if a project plan is in place). It is recommended that there be a compliant contract in place in addition to a sampling plan to define client quality objectives. A sampling plan should include:

• Client Contract Record

• Analyses requested

• Sample designation (Medical or Recreational)

• If applicable, standing or individual subcontract agreements by the client and subcontract lab

• Sampling schedule and transport schedule

• Personnel assigned to sampling and transport

• Name and address of processor, including licensee or registrant number

• Any certifications of Control Study and expiration date issued by OHA or the Commission

• Product type

• Unique laboratory Project Number or ID #, METRC Lot ID #, and/ or OHA process lot ID # as designated

• Total Mass or number of units of sale in process lot

• Applicable SOPs for sample type

• Statistical methods or calculators used for sampling design

• List of necessary equipment

Sampling Records/Field Data

The sampling SOP shall use these protocols as minimum requirements and must include additional detail specific to laboratory procedures. Any changes, including use of a selected option, shall be documented and included on the sampling form. In cases where the published method has been modified or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Any deviations and amendments to the sampling plans or SOPs must be well documented at the time of occurrence and, when possible should be agreed upon by the client preferably before sampling occurs. Sampling records must include at least the following:

• Unique laboratory Production Lot Number or ID #, METRC Lot ID #, and/ or OHA process lot ID # as designated

• Total mass or number of units of sale in process lot

• Total number of containers

• Sample containers collected (Type and Number)

• Total mass sampled

• Number of sample increments

• If applicable, number of sample increments combined into primary and field duplicate samples collected

• Number of total primary and field duplicate samples

• Sampling Methodology (Reference and lab SOP IDs and revision)

• Description and IDs of equipment used;

• Balance identification and calibration information (where applicable)

• Identify any environmental conditions or other considerations that may impact data

• Identify any deviations from the sampling plan or SOP

• Sampling locations

• Date sampled

• Sampler's identification and signature

• Name of responsible party for the production lot and transport information

• Receiving laboratory and types of tests required or requested

• *Note: In the event that the production lot* or *registrant number is not available, refuse to sample.*

• Client Name

• Client License/Registration #(s)

• Facility address

• Batch Unique Identification number

• Storage conditions of the batch (if available, such as but not limited to)

• Temperature

• Humidity

• Containers

• Mass of batch or process lot

• Requested Analyses

• Applicable Control Study Certificate, agency documentation, and expiration dates of these.

If any of the above information requested on the sampling report is unavailable, indicate "N/A" in the appropriate space. All sampling reports must be signed by the sampler.

Chain of Custody

While procuring the sample, in the absence of METRC procedures and print-outs that contain the below information, the laboratory must create a Chain of Custody form with the following information:

• Sampler's name

• Lab License Number

• Sample Identification (Lab ID number) if assigned before arrival at laboratory

• Sampling Date/Time

• Sample IDs and container ID of increment or composite samples

• Final Mass of each sample ID

• Custody transfer signatures

• Custody Transfer Dates/Times

If any of the other above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space. All chain of custody forms must be signed by the sampler.

Sampling process for the Control Study required in OAR 333-007-0440

1. Ensure that processor or processing site has completed the control study requirements under OAR 333-007-0440(1).

2. Locate the batch of cannabis product to be sampled for the control study.

3. Review the batch label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot number is not available or does not match the written request for the control study.

4. Visually inspect the batch to assess uniformity across units for sale.

5. Determine the size of batch by reviewing the written request for the control study.

6. Determine the number of sample increments necessary based on total size of the batch. The minimum increments necessary are in OAR 333-007-0360, Exhibit B, Tables 5 and 6. For cannabinoid products each sample increment consists of an entire unit of sale. Additional increments may be required to ensure that sufficient quantity of material is available for all required tests.

7. Additional information and requirements for sampling concentrates, extracts and products is in the section below.

8. Sample increments taken for a control study may not be combined into a composite sample.

Once a process lot of a product has successfully completed a control study and the control study has been certified by the Authority or the Commission, only one primary sample and one field duplicate sample need to be collected from future process lots of that product as specified in OAR 333-007-0360 and 333-007-0440. Sample increments for the primary sample and the field duplicate sample for cannabinoid concentrates and extracts are specified in OAR 333-007-0360(2)(c), Exhibit B, Table 7. Sample increments for the primary sample and the field duplicate sample for cannabinoid products are specified in OAR 333-007-0360(2)(d).

Sample increments being collected for a control study, or with a control study certification must be obtained, as described below in this protocol.

Sampling for concentrates, extracts and products

1. Locate the finished cannabinoid concentrate, extract or product batch to be sampled.

2. Review the container label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot numbers are not available.

3. Determine if the sample matrix is a liquid, semi liquid, or solid either in bulk form or in packaged units. Determine and record the total batch weight or volume and the number of containers comprising the batch. If the product is already in final packaging, determine and record the total number of final package units. Visually inspect the batch for uniformity and/or deviations from the manifest or elements that call the site specific or process specific sampling plan into question. Do not sample if there are deviations from the manifest or questions about the statistical certainty of the sampling plan.

4. Establish which tests will be performed. Ensure sufficient sample increments are taken to meet sample size requirements determined sampling plan and record the number of increments collected. The minimum sample amount is determined by the analytical method(s) being performed but can be no less than number of increments in OAR 333-007-0360, Exhibit B, Tables 5 and 6 unless the product has successfully completed a control study. If the cannabinoid concentrate, extract or product has successfully completed a control study sample increments can be combined into one primary sample and one field duplicate sample. The sample increments for the primary sample and the field duplicate sample for cannabinoid concentrates and extracts are in OAR 333-007-0360, Exhibit B, Table 7. The sample increments for the primary sample and the field duplicate sample for cannabinoid products is in OAR 333-007-0360(2)(d).

5. Ensure that appropriate equipment and containers are used for the tests being performed. For residual solvent analysis, use glass amber containers that can be properly sealed to prevent the loss of solvent gas and minimize the headspace remaining in the sample container.

6. Select the appropriate sampling tool to ensure that it reaches all portions of the batch.

7. Collection instruments must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools which appear to be dirty or otherwise compromised shall not be used. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling.

a. *Note: Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler is required to bring enough sets of sampling equipment to use a new set at each facility visited. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.*

8. Once taken, seal and label the sample increments, composite sample, primary sample or field duplicate sample, as applicable with the following minimum requirements:

a. Laboratory licensee number

b. Unique identifier for sampling event

c. Sampling date and name of sampler

d. Processor's license or registration number

e. Process lot and batch numbers

f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12 point font

9. Apply a custody seal to the sample container in a manner that prevents the marijuana item from being tampered with prior to testing.

10. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in 2009 TNI EL V1M2 5.8.1 through 5.8.7.

11. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.

Demonstration of Capability

Prior to acceptance and institution of each method for which data will be reported, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method; and 2) when the method has not been performed by the laboratory within a 12-month period.

This procedure shall employ one of the following approaches to demonstrating capability:

• Comparison of replicate samples within defined %RSD acceptance criteria.

• Comparison of a sample collected to that of one collected by personnel with an existing IDOC within defined %RPD acceptance criteria.

Thereafter, ongoing continuing demonstration of capability (CDOC) as per the quality control requirements referenced in the method is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

Sampler qualifications

Basic qualifications for samplers of marijuana items are:

• Physically able to perform the duties of a sampler

• No conflict of interest

• Employed by an ORELAP accredited laboratory

• Pass initial and ongoing demonstrations of capability

• Licensed to transport the required quantity of *marijuana items*

Required education and training for samplers:

Initial classroom training: 8-hours of training, including principles, procedures, and policies of sampling; Initial Training must be performed by an Instructor that has demonstrated competency in performing and instructing on the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.

Field or on-the-job training: 8-hours of training on various sampling techniques.

Continuing education: 8-hours of periodic refresher training annually.

Field Audits

The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits should be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the rules and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.

When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.

Auditing checks

Using audit checklists:

• Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol.

• Observe the sampler conducting sampling procedures.

• Obtain check samples taken by an auditor of process lot previously sampled by the sampler for evaluation and comparison of results.

• Record any deficiencies and initiate corrective action.

References

NDA (2006). *Standard operating procedure on sampling and analysis of agricultural products of plant origin to determine agrochemical residue levels and risk management as part of the export inspection and certification in terms of agricultural products standards act.*

FDA (2015). *Salmonella sampling plan*. Investigations Operations Manual 2015. ASTA.

Clean, Safe Spices. Guidance from the American Spice Trade Association.

FDA, *Guidelines for Food Spice Labeling.* Code of Federal Regulations Title 21, Volume 2.http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=101.2 2)

FDA. The Food Defect Action Levels: *Levels of natural or unavoidable defects in foods that present no health hazards for humans.* Code of Federal Regulations Title 21, Part 110.

Sampling and Sample Handling Working Group FDA, AAFCO, AFDO, APHL and Industry, October 2015. *Good Samples: Guidance on Obtaining Defensible Samples*.

National Environmental Field Activities Program (NEFAP); TNI EL Standard (2009), Volume 1 *Management and Technical Requirements for Laboratories Performing Environmental Analysis.*

http://www.nelac-institute.org/content/CSDP/standards.php

Oregon Administrative Rules, *Marijuana Labeling, Concentration limits, and Testing,* Chapter 333, Division 7.

Oregon Administrative Rules, *General Requirements Applicable to all Marijuana Licensees,* Chapter 845, Division 25.

Standard Methods 20th Edition (1998); 1020 Quality Assurance

Technical and Regulatory Guidance, Incremental Sampling Methodology, February 2012, Prepared by The Interstate Technology & Regulatory Council, Incremental Sampling Methodology Team

Appendix 1 - Definitions

Authority means Oregon Health Authority

Batch means a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.

CBD means Cannabidiol.

Chain of Custody means the chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

Commission means the Oregon Liquor Control Commission.

Composite sample means a sample containing all primary samples taken from a batch.

Container means a sealed, hard or soft bodied receptacle in which a marijuana item is placed or a physical division of an extract or concentrate process lot for random sampling.

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.

Decision Unit (DU) or sampling unit means the material from which the primary sample(s) is collected and to which the inference(s) is made.

Equipment blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate cleaning procedure or between sampling batches to demonstrate lack of contamination.

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.

Fundamental Sampling Error (FSE) means the results from compositional heterogeneity, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

Heterogeneity means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

Homogeneous means uniform in composition within recognized tolerances.

Label means a tag or other device attached to or written, stamped, or printed on any container or accompanying any batch in bulk stating all required batch information.

Laboratory means a laboratory that is accredited under ORS 438.550 to 438.590 to s a m p l e o r conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS 475B.560.

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include industrial hemp, as defined in ORS 571.300.

Marijuana item means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

ORELAP means the Oregon Environmental Laboratory Accreditation Program.

Primary Sample means a sample composed of sample increments and tested for the required analysis methods.

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).

Registrant means a person registered with the Authority under ORS 475B.810, 475B.840, or 475B.858.

Relative Percent Difference means comparing two quantities while taking into account the "sizes" of the things being compared. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

Relative standard deviation means the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If any results are <LOQ, the absolute value of the LOQ is used in the equation.

Standard Deviation

Relative Standard Deviation

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

B = mean of n values.

Representative Sample means a sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are

proportionally represented. In essence, the sample must mimic the population in every way, including distribution of the individual items or members of the population.

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

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.

Sample Quality Criteria (SQC) means a series of statements that clarify program technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed means secured to provide authenticity or integrity.

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.

THC means **tetrahydrocannabinol**

Transport Blank means a sample of analyte-free media which has been carried to the field and returned to the lab used to demonstrate that the process did not add volatile contamination in solvent analysis.

Usable marijuana means the dried leaves and flowers of marijuana. Usable marijuana does not include the seeds, stalks and roots of marijuana or waste material that is a byproduct of producing or processing marijuana.

AMEND: 333-064-0110

RULE TITLE: Reporting Marijuana Test Results

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Removing language that states test results expire after one year.

RULE TEXT:

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.

(2) A test report must clearly identify for the licensee or registrant:

(a) Whether a sample has exceeded an action limit for an analyte in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 or 4, or has otherwise failed a test as described in OAR 333-007-0300 to 333-007-0500.

(b) A "detected" pesticide result as required in section (6) of this rule.

(c) The batch unique identification number required under OAR 333-007-0350 and the test batch number associated with the samples tested, as required by OAR 333-064-0100.

(d) Identification of the test as a compliance test or a quality control or research and development test.

(e) If applicable, a statement that the test was done on a sample from a remediated marijuana item.

(3) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-0500 except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:

(a) Into the Commission's seed to sale tracking system if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8; and

(b) To the Authority electronically at www.healthoregon.org/ommp if performing testing for a registrant, along with a copy of the test order information required in OAR 333-007-0315, regardless of whether the laboratory is also reporting into CTS on behalf of a registrant that is subject to CTS tracking under OAR chapter 333, division 8.

(4) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0500 that have not been reported under section (3) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8.

(5) A laboratory must determine and include on each test report its limit of quantification (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3 and 333-007-0410 Table 4.

(6) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 5:1 and meets identification criteria with a result of "detected." This additional reporting is not required if the laboratory's LOQ is less than or equal to one half of the action level in Table 3.

(7) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.

(a) Batch quality control samples are the method blank and laboratory control sample.

(b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.

(8) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (3) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.

(9) If requested by the Authority, a laboratory must report sampling and testing information to the Authority, in a manner prescribed by the Authority.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

ADOPT: 333-064-0120

RULE TITLE: Proficiency Testing for Laboratories Accredited for Cannabis Testing

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adopting language regarding requirements for cannabis laboratory proficiency testing.

RULE TEXT:

The purpose of a proficiency testing (PT) study is to provide a means for ORELAP to evaluate a laboratory's performance, under specified conditions related to a given set of criteria in a specific area of accreditation, through analysis of PT samples provided by an external source.

(1) A laboratory accredited to test marijuana items must at all times have two successful PT studies out of the most recent three attempts for each field of accreditation for which the laboratory holds accreditation.

(a) The closing dates of a PT study for a particular field of accreditation can be no more than seven months apart.

(b) The opening date of a PT study for a particular field of accreditation must be at least seven calendar days after the closing date of the previous PT study for the same field of accreditation.

(2) For purposes of this rule a PT study is a scheduled PT study or a supplemental PT study.

(3) When a laboratory submits its PT study results to the PT vendor, the laboratory must:

(a) Ensure that the information provided to the vendor reflects accurate information about the laboratory that corresponds to the information in the laboratory's accreditation or application for accreditation, including but not limited to:

(A) The laboratory's name and address;

(B) The laboratory's ORELAP ID number; and

(C) The method and analyte codes.

(b) Instruct the PT vendor to send the PT results directly to ORELAP.

(4) Any of the following will be considered to be an unsuccessful PT study and if a study was done, may not be counted toward the laboratory's PT history of the most recent three attempts:

(a) If a PT study for a particular field of accreditation is not performed within seven months, the laboratory will be charged with a failed study for each analyte.

(b) A PT study for a particular field of accreditation that has an opening date less than seven days from the closing date of the previous PT study for that same field of accreditation.

(c) Information on study results received from the vendor does not match any of the items in 333-064-0120(3).

(5) For pesticide and potency analyses in usable marijuana, a laboratory must use PT samples made with a usable marijuana matrix.

(6) In accordance with ORS chapter 183, the Oregon Health Authority may:

(a) Suspend the affected field of accreditation if a laboratory fails to comply with this rule.

(b) Revoke the affected field of accreditation if a laboratory fails three consecutive PT studies or fails to participate in a PT study as is required by these rules.

(7) For purposes of this rule a successful PT study means the testing results have been evaluated as acceptable.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555

ADOPT: 333-064-0130

RULE TITLE: Cannabis Laboratory Violations and Enforcement

NOTICE FILED DATE: 10/18/2018

RULE SUMMARY: Adopting language regarding cannabis laboratory violations and enforcement.

RULE TEXT:

(1) In addition to any violation of these rules, it is a violation for a laboratory accredited for cannabis sampling or analysis to:

(a) Falsify any documentation that is required by these rules or the laboratory's accredited policies and procedures.

(b) Fail to collect the information required for ordering a test under OAR 333-007-0315 or 333-007-0440.

(c) Fail to comply with any applicable TNI standard.

(d) Report false or misleading information to the Authority or the Commission.

(2) For a violation of these rules, including any violation in section (1) of this rule, ORELAP may:

(a) Impose a civil penalty not to exceed $500 per day per violation against a laboratory accredited for cannabis sampling or analysis; and

(b) Deny, suspend or revoke accreditation of a laboratory accredited for sampling or analyzing cannabis.

(3) A laboratory that has its accreditation revoked under these rules may not reapply for accreditation for one year from the date the revocation is effective.

STATUTORY/OTHER AUTHORITY: ORS 475B.555

STATUTES/OTHER IMPLEMENTED: ORS 475B.555