333-064-0025

Definitions

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) "Adult use cannabinoid" has the meaning given that term in OAR 333-007-0310.

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

(4) "Artificially derived cannabinoid" has the meaning given that term in OAR 333-007-0310.

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

(6) "Batch" means:

(a) For sample analysis, this term has the meaning assigned in the TNI Standard which is a group of samples that are prepared or analyzed together in the laboratory with the same process and personnel, using the same lot(s) of reagents.

(A) A preparation batch is composed of 1 to 20 environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing the first and last sample in the batch to be 24 hours.

(B) An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples.

(b) For cannabis sampling~~:~~

~~(A) A quantity of marijuana or usable marijuana from a harvest lot; or~~

~~(B) A quantity of cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item from a process lot.~~ this term has the same meaning given that term in OAR 333-007-0310.

(c) For psilocybin sampling, this term has the same meaning given that term in OAR 333-333-1010.

(7) "Biological tissue" as a matrix means samples of biological tissue, excluding those of human origin, and includes:

(a) Usable marijuana and hemp samples for compliance testing.

(b) Psilocybin-containing dried fungal tissue, such as fruiting bodies or hyphae.

(8) “Cannabinoid product” has the meaning given that term in OAR 333-007-0310.

(9~~8~~) "Cannabis" has the meaning given that term in OAR 333-007-0310.

(10~~9~~) "Cannabis sampling" means an activity related to obtaining a representative sample of a marijuana item or industrial hemp-derived vapor item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.

(11~~0~~) "Cannabis Tracking System" or "CTS" has the meaning given that term in OAR 333-007-0310.

(12~~1~~) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

(13~~2~~) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-85-2.

(14~~3~~) "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.

(15~~4~~) "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.

(16~~5~~) "Commission" means the Oregon Liquor and Cannabis Commission.

(17~~6~~) "Delta-8-tetrahydrocannabinol" or "Delta-8 THC" means (6aR, 10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.

(18~~7~~) "Delta-9-tetrahydrocannabinol" or "Delta-9 THC" means (6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 1972-08-3.

(19~~8~~) "Delta-9-tetrahydrocannabinolic acid" or "Delta-9-THCA" means (6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-2-carboxylic acid, Chemical Abstracts Service Number 23978-85-0.

(2019) "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.

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

(221) "Finished cannabinoid concentrate or extract" has the meaning given that term in OAR 333-007-0310.

(232) "Finished cannabinoid product" has the meaning given that term in OAR 333-007-0310.

(243) "Finished inhalable cannabinoid product" has the meaning given that term in OAR 333-007-0310.

(254) "Industrial hemp-derived vapor item" has the meaning given that term in OAR 333-007-0310.

(265) "Homogenization" means physically manipulating a sample to make the sample's material uniform in composition and properties throughout, and ~~including but not limited to~~ reducing particle size to a ~~fine~~ uniform ~~powder~~ material for biological tissue and solid ~~materials~~ matrices or combining all layers or phases of a liquid or semi-solid sample into a uniform substance.

(27) "ISO / IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrochemical Commission (IEC).

(28) "ISO / IEC 17043" means the general requirements established by the ISO / IEC for proficiency testing. Available at https://www.iso.org/home.html.

(296) "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.

(3027) "Marijuana item" has the meaning given that term in OAR 333-007-0310.

(3128) "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.

(32~~29~~) "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.

(33~~0~~) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.

(34~~1~~) "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.

(35~~2~~) "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.

(36~~3~~) "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. During a period when the Governor has declared a state of emergency, when an on-site visit would jeopardize the health and safety of the participants, assessments may be conducted remotely by electronic means to evaluate the facility for conformance to the TNI Standards.

(37~~4~~) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.

(38~~5~~) "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.

(39~~6~~) "Proficiency testing (PT)" means:

(a) For all fields of accreditation, except as outlined in subsection b, the analysis of samples obtained from providers that meet the TNI standards for PT providers.

(b) For cannabis and psilocybin fields of accreditation means the analysis of samples obtained from an ORELAP approved ISO / IEC 17043 accredited PT provider or a PT sample made by the Oregon Department of Agriculture Cannabis Reference Laboratory.

(c) 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.

(4037) "Psilocin analyte" means 4-hydroxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-53-6.

(4138) "Psilocybin analyte" means 4-phosphoryloxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-52-5.

(4239) "Psilocybin product" has the meaning given that term in OAR 333-333-1010.

(430) "Psilocybin Tracking System" or "PTS" has the meaning given that term in OAR 333-333-1010.

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

(452) "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.

(463) "Replicate sample" is a sample in addition to the primary and duplicate samples that consists of the same number of increments taken in the same manner as the primary and duplicate samples.

(474) "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.

(485) "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.

(496) "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.

(5047) "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.

(5148) "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, and includes:

(a) Cannabinoid products and concentrates or extracts and industrial hemp-derived vapor items as defined in OAR 333-007-0310.

(b) Psilocybin products as defined in OAR 333-333-1010 with the exception of dried fruiting bodies and hyphae.

(5249) "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.

(53) “Target potency” has the meaning given that term in OAR 845-025-7000.

(540) "Total ~~Potential Psilocin~~Psilocybin Equivalent" means the sum of the ~~psilocin~~ psilocybin analyte concentration and ~~0.719~~1.4 times the ~~psilocybin~~ psilocin analyte concentration. This number is the maximum theoretical concentration of ~~psilocin~~ psilocybin in the sample.

(551) "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.

(562) "TNI Standards" means the adopted TNI Standards (© 2016 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. Available at www.nelac-institute.org

(573) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0160.

(584) "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.

(595) "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.

(6056) "Whole fungi" has the meaning given that term in OAR-333-333-1010.

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150, 448.280, 475C.544, 475C.560, 475A.590 & 475A.606
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280, 475C.544, 475C.560, 475A.590 & 475A.606
History:
PH 207-2022, amend filed 12/27/2022, effective 12/27/2022
PH 24-2022, amend filed 03/15/2022, effective 03/31/2022
PH 95-2021, amend filed 12/29/2021, effective 01/01/2022
PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 85-2020, amend filed 12/23/2020, effective 01/01/2021
PH 54-2020, temporary amend filed 06/05/2020, effective 06/05/2020 through 12/01/2020
PH 35-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 17-2016, f. & cert. ef. 6-7-16
PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16
PH 6-2011, f. & cert. ef. 8-9-11
PH 8-2005, f. 6-1-05, cert. ef. 7-1-05
PH 23-2004, f. & cert. ef. 7-1-04
PH 20-2003, f. 12-02-03, cert. ef. 12-08-03
PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04
PH 5-2003, f. 5-15-03, cert. ef. 7-1-03
OHD 16-2002, f. & cert. ef. 10-10-02
OHD 1-2001, f. & cert. ef. 1-17-01
OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0100
Cannabis Sampling Procedures and Testing

(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 and industrial hemp-derived vapor items sampling policies and procedures, accredited by the Oregon Environmental Laboratory Accreditation Program (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 Volume 1 Module 2 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 Revision 4.1; and

(ii) Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items: ORELAP-SOP-002 Revision 4.3.

(F) Ensure that only the finished cannabinoid concentrate, extract, product, or industrial hemp-derived vapor item is sampled if testing on the finished cannabinoid concentrate, extract, product, or industrial hemp-derived vapor item is required under OAR 333-007-0330 , ~~and~~ OAR 333-007-0340, or OAR 333-007-0341.

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

(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana or industrial hemp-derived vapor item 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 Cannabis Tracking System (CTS) tracking under ORS 475C.871, record the sampling and transfer information

in the ~~Oregon Liquor and Cannabis Commission's (Commission's) seed to sale system~~CTS, as required by the Oregon Health Authority (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 and potential reanalysis 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, duplicate sample, and replicate sample 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 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 ~~shall~~ must be combined into a single sample by a laboratory prior to testing.

(B) Prior to testing, a laboratory ~~shall~~ must combine sample increments from a batch of a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item;

(i) Increments from a primary sample are combined into a single sample.

(ii) Increments from a duplicate sample are combined into a single sample.

(iii) Increments from each replicate sample are combined with each other but material from separate replicate samples are not combined.

(3) Sample handling and homogenization

(a~~C~~) Prior to any testing or subsampling except as described in subparagraph (B~~i~~) of this paragraph, the entire combined sample except as described in subparagraph (D~~iii~~) of this paragraph must undergo the laboratory's homogenization process.

(A) The laboratory's homogenization process for usable marijuana must make the entire sample uniform to less than or equal to 1.0 mm. The laboratory must not remove stems, seeds, or leaf material prior to the homogenization process. The laboratory must perform and document an initial validation to demonstrate the laboratory's homogenization process for usable marijuana achieves a sample uniformity of less than 1.0 mm.

(B~~i~~) If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis.

(C~~ii~~) Potency, pesticides, mycotoxins, solvents, and heavy metals analysis ~~shall~~ must not be performed on material subsampled prior to homogenization steps.

(D~~iii~~) Prior to homogenization, the filter or tip ~~shall~~ must be removed from pre-rolled usable marijuana and finished inhalable cannabinoid products that include a filter or tip. Filters and tips are considered non-consumed packaging and are not part of the sample for the purpose of homogenization or testing. All other components of the pre-roll must be included in the laboratory's homogenization process.

(b~~D~~) Sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360 using the process described in ORELAP-SOP-001 Revision. 4.1.

(c~~E~~) Portions of homogenized samples that are combined for testing as permitted by OAR 333-007-0360(1)(c) ~~shall~~ must use the laboratory's formal subsampling method to produce a proportionally representative sample from each batch involved.

(A) To combine a homogenized sample for testing as permitted by OAR 333-007-0360(1)(c), a proportionally representative amount of material must be withdrawn from

each homogenized sample and then the withdrawn material from each sample must be combined to produce the combined sample.

(B) The amount of material withdrawn from each sample to form the combined sample must be documented.

(dg) Sample replicate analysis for concentrates, extracts, finished inhalable cannabinoid products, and industrial hemp-derived vapor items.

(A) When replicate samples are required per OAR 333-007-0360 Exhibit B Table 7, each sample ~~shall~~ must be analyzed individually for residual solvents as described in OAR 333-007-0410 and adult use cannabinoids and CBD as described in OAR 333-007-0430.

(B) Two samples ~~shall~~ must be randomly selected according to the laboratory's policy and procedures and analyzed individually for the remaining required analyses as described in OAR 333-007-0330, 333-007-0341, and 333-007-0342.

(C) Adult use cannabinoid and CBD results for the batch or process lot are reported as the calculated ~~average~~ mean result from all sample replicates.

(43) Compliance testing validity.

(a) When testing a sample for the required microbiological compliance tests as described in OAR 333-007-0390, a laboratory must comply with additional method validation as follows:

(A) Run a negative control in accordance with TNI Standard requirements to demonstrate the procedure is free of microbiological contaminants that prevent accurate testing.

(B) Run a positive control in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the positive control means accurate identification and quantitation of all organisms required in OAR 333-007-0390.

(C) Demonstrate acceptable performance as described in the manufacturer's instructions of an internal amplification control (IAC) in each sample analyzed by a polymerase chain reaction (PCR) method. In the case of a positive result for a required organism in a sample with an unacceptable performance of the IAC, follow the manufacturer's instructions on interpretation of acceptability.

(b) When testing a sample for the required chemistry compliance tests as described in OAR 333-007-0400 to 333-007-0415 and 333-007-0425 to 333-007-0430, a laboratory must comply with additional method validation as follows:

(A) Run a method blank in accordance with TNI Standard requirements to demonstrate the procedure is free of contaminants at or above the limit of quantitation (LOQ).

(B) Run a laboratory control standard (LCS) in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the LCS means percent recovery for all regulated analytes ~~are~~ must be within the limits specified in Exhibit C, Table 1.

(i) The LCS may be made and characterized by the laboratory for potency testing only. The LCS characterization protocol must include at least seven replicates. The laboratory must calculate and document the mean and standard deviation of the replicates. The assigned value of the characterized LCS must be the calculated mean of the replicates.

(ii) If characterized LCS fails during routine analysis, and the laboratory intends to recharacterize or remake the characterized LCS, the laboratory must perform and document an investigation into the cause of the failure prior to recharacterizing the LCS, to demonstrate the LCS failure is not due to laboratory error.

(C) Run an initial calibration verification (ICV) for each initial calibration in accordance with TNI Standard requirements. Acceptable performance of the ICV means percent recovery for all regulated analytes must be within the limits specified in Exhibit C, Table 1.

(D) Run continuing calibration verification (CCV) in accordance with TNI Standard requirements. Acceptable performance of a CCV means percent recovery for all regulated analytes must be within the limits specified in Exhibit C, Table 1.

(E~~C~~) Analyze duplicate samples with a precision limit of 10.0 percent relative percent difference (RPD), if duplicates are required as specified in OAR 333-007-0360 and analyze all replicate samples with a precision limit of 10.0 percent relative standard deviation (RSD), if replicates are required as specified in OAR 333-007-0360.

(5~~4~~) Calculating total delta-9 THC and total CBD.

(a) Total delta-9 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 * 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 * M CBDA.

(c) Each test report must include the results for delta-8 THC, total delta-9 THC, and total CBD.

(65) Report delta-8 THC, total delta-9 THC, and total CBD for useable marijuana as dry weight. A laboratory must analyze the sample as received and report delta-8 THC, total delta-9 THC and total CBD content by dry weight calculated as follows:

P delta-8 THC(dry) = P delta-8 THC(wet) / [1-(P moisture/100)]

P total delta-9 THC(dry) = P total delta-9 THC(wet) / [1-(P moisture/100)]

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

(7) When testing marijuana or useable marijuana for potency per OAR 333-007-0430 the collected sample may be analyzed more than once by the same laboratory. Once the sample is tested by a laboratory for potency, the laboratory may not subcontract additional potency testing to another laboratory.

(a) All potency results obtained must be used to calculate the mean result of each adult use cannabinoid and CBD analytes required per OAR 333-007-0430.

(b) A laboratory must have a minimum of three potency test results to calculate a mean result as the reported adult use cannabinoid and CBD results.

(c) If the laboratory determines a potency result is an outlier, the laboratory must have a documented scientific justification, such as Grubbs Outlier Test, for excluding the outlier result. The outlier result must be excluded for all potency analytes, not just the potency analytes that are determined to be outliers.

(86) Calculating RPD and RSD.

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

Relative Percent Difference

%RPD=|(sample–duplicate)|/((sample+duplicate)/2) * 100

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

Standard Deviation

S= √(∑((xi–x)^2)/(n–1))

Relative Standard Deviation

%RSD= (S/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 Limit of Quantitation (LOQ) the absolute value of the LOQ is used in the equation.

(e) The laboratory ~~shall~~ must not substitute the LOQ for individual components of a totaled result, such as total delta-9 THC or total Hexanes, in the calculation of the totaled result for the purpose of calculating RPD or RSD.

(~~9~~7) Tentative Identification of Unknown Compounds.

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates, extracts, or industrial hemp-derived vapor items for solvents the laboratory ~~shall~~ must have an established procedure for achieving tentative identification of unknown compounds in the sample. A tentatively identified compound (TIC) means an unknown chromatographic peak that is neither included in the list of analytes the laboratory is testing for nor expected to be naturally found in cannabis concentrates, extracts, or industrial hemp-derived vapor items such as terpenes.

(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds). Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to the database library spectrum.

(c) Upon written request from the overseeing agency of the licensee or registrant, a laboratory ~~shall~~ must report to the licensee or registrant and the Authority or the Commission all tentatively identified compounds (TICS) that meet the identification criteria in subsection (7)(b) of this rule.

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

(B) If a laboratory does not use internal standards, TICs ~~shall~~ must be reported as "detected" and apparent relative concentration ~~shall~~ must be judged based on peak area.

(8) A laboratory must provide:

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

(b) A sample or a portion of a sample to the Department 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~~CTS.

(10~~9~~) A laboratory performing tests for a licensee or a registrant required to use CTS under ORS 475C.871 must enter any information required by the Commission or the Authority in CTS.

(11~~0~~) 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, permit a laboratory to deviate from the TNI Standard in order to comply with OAR 333-007-0300 to 333-007-0600 and these rules based on the state's needs. Permission to deviate from the TNI Standard must be in writing from the Authority.

(12) A laboratory must be able to demonstrate that its limit of quantitation (LOQ) for all matrices in compliance testing is:

(a) Less than or equal to one-half of any action level established in OAR 333-007-0400, 333-007-0410, 333-007-0415, and 333-007-0425 Exhibit A, Tables 3, 4, 8, and 9 except for as outlined in 333-064-0110(6); and

(b) For delta-9 THC concentration less than or equal to 0.150 percent;

(c) For THC-A concentration less than or equal to 0.150 percent;

(d) total delta-9 THC concentration less than or equal to 0.150 percent; and

(e~~c~~) For delta-8 THC concentration less than or equal to 0.150 percent.

(14) When performing calculations, a laboratory must not round any values during intermediate steps of a calculation. Rounding may only occur after all calculation steps have been completed.

(15) A laboratory is prohibited from the following actions during testing:

(a) fabricating, falsifying, or misrepresenting data, including but not limited to creating data for an analysis that was not performed;

(b) unwarranted manipulation of samples or analytical conditions, including unjustified dilution of samples or changing the instrument conditions for sample analysis from the conditions used for standard analysis;

(c) unwarranted manipulation of software, including forcing calibration or QC data to meet acceptance criteria, removing software operational codes indicating analyst manipulation of results, changing parameters to avoid displaying appropriate qualifiers, inappropriately subtracting background, or improperly manipulating the chromatographic baseline;

(d) turning off, or otherwise disabling, electronic instrument audit tracking functions;

(e) misrepresenting or misreporting quality control samples, including representing spiked samples as being digested or extracted when a digestion or extraction was not performed;

(f) substituting previously generated analysis for a non-compliance calibration or quality control analysis;

(g) failing to prepare or analyze method blanks (MB), matrix spikes, and laboratory control samples (LCS) in the same manner that samples are prepared or analyzed;

(h) inappropriately preparing and analyzing quality control samples;

(i) deleting or failing to record quality control data outside acceptance criteria to conceal the fact that calibration or other quality control analysis were outside acceptance criteria;

(j) performing improper manual integrations;

(k) concealing a known analytical or sample problem;

(l) removing failed quality control analysis from the record of an analytical sequence;

(m) excluding known quality control failures from the test report;

(n) observing out-of-compliance equipment conditions, then adjusting the equipment into compliance and recording only the compliant observation;

(o) performing repeated or additional testing for the purpose of achieving a preferred result or target potency result;

(p) performing repeated testing or additional testing and reporting the calculated mean results for any testing other than potency in useable marijuana; and

(q) performing repeated or additional testing for the purpose of preventing the sample from failing for an action limit described in:

(A) Microbiological contaminants in accordance with OAR 333-007-0390;

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

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

(D) Heavy metals in accordance with OAR 333-007-0415;

(E) Water activity and moisture content in accordance with OAR 333-007-0420;

(F) Mycotoxins in accordance with OAR 333-007-0425;

(G) Adult use cannabinoids and CBD in accordance with OAR 333-007-0430 and OAR 333-007-0430(4); and

(H) Failed test samples in accordance with OAR 333-007-0450.

(163) 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.

(174) Sample material retention. A laboratory ~~shall~~ must retain all of the unused sample material for a minimum of 30 calendar days after reporting results into the CTS.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 475C.544, 475C.560 & 438.620
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 475C.544, 475C.560 & 438.620
History:
PH 14-2026, amend filed 01/13/2026, effective 01/20/2026
PH 18-2025, temporary amend filed 09/23/2025, effective 09/23/2025 through 03/21/2026
PH 10-2025, minor correction filed 04/21/2025, effective 04/21/2025
PH 68-2024, amend filed 07/09/2024, effective 07/23/2024
PH 24-2022, amend filed 03/15/2022, effective 03/31/2022
PH 95-2021, amend filed 12/29/2021, effective 01/01/2022
PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 85-2020, amend filed 12/23/2020, effective 01/01/2021
PH 43-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-064-0110

Reporting Cannabis Test Results

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

(2) A laboratory must ensure that all test reports ~~must~~ clearly:

(a) Identify for the licensee or registrant:

(A) Whether a sample has exceeded an action limit for an analyte in OAR 333-007-0400, 333-007-0410, 333-007-0415, and 333-007-0425 Exhibit A, Tables 3, 4, 8, or 9, 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. If the test is ~~not~~ for compliance and meets Oregon compliance test standards in Division 7 and these rules, the report ~~shall~~ must ~~indicate clearly~~ on the first page state ~~the testing was for quality control or research and development~~ ".This test report meets Oregon compliance testing standards."

(E) If applicable, ~~a statement~~ that the test was done on a sample from a remediated marijuana item or industrial hemp-derived vapor item.

(F) For potency that was tested multiple times on useable marijuana, as outlined in OAR 333-064-0100, all test results and batch quality control results must be listed on the report. The reported potency results for each analyte must be the calculated mean of all analyses.

(G) If required in OAR 333-007-0360, OAR 333-007-0140, OAR 333-007-0430, and OAR 333-064-0100, the average result of primary, duplicate, and replicate samples, as applicable.

(H) If applicable, the relative percent difference (RPD) or relative standard deviation (RSD) of primary, duplicate, or replicate samples as required in OAR 333-007-0410, 333-007-0430, and OAR 333-064-0100.

(I) Identification of any failed tests on the first page of the test report.

(J) If applicable for cannabinoid products, the target potency, serving sizes and unit of sale, density or mass, or volume of intended serving sizes and unit of sale as provided to the laboratory under OAR 333-007-0315.

(K) Test results and quality control results in a form containing the same or more significant figures as each action level for the analyte being tested in accordance with OAR 333-007-0400, OAR 333-007-0410, OAR 333-007-0415, OAR 333-007-0420, and OAR 333-007-0425 and OAR 333-064-0100 Exhibit C.

(L) Quantitative quality control results in percent recovery.

(b) Include all information required in Volume 1 Module 2 section 5.10 of the 2016 TNI Standard with the following exceptions:

(A) The address of the customer; and

(B) The location of sampling, including any diagrams, sketches, or photographs.

(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 laboratory is reanalyzing the sample under OAR 333-007-0450:

(a) Into the Cannabis Tracking System (CTS) 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 Oregon Health Authority (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.

(c) If the laboratory discovers that an error has occurred after reporting, an amended report ~~shall~~ must be generated and communicated to the licensee or registrant, the Oregon Liquor and Cannabis Commission (Commission) for licensees, and the Authority for registrants. The laboratory ~~shall~~ must ensure that results entered into the CTS are accurate and updated if necessary to reflect the amended report. The laboratory ~~shall~~ must ensure that the amended report, communication, and updates to CTS as described in this rule are completed within 48 hours of learning of the error.

(d) The laboratory must have a written procedure for amending test reports when an error is discovered. Prior to issuing the amended report, the laboratory must supply to the Authority or the Commission:

(i) A letter from the laboratory's Technical Manager, or their designee, confirming the laboratory mistake or error and agreeing to the invalidation request;

(ii) Complete sample identification, date and time of sampling event, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;

(iii) Complete description of the error alleged to have invalidated the result(s);

(v) Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question;

(vi) A corrective action plan that contains a cause analysis of the laboratory accident or error, the corrective actions that will take place, and the date the problems will be corrected; and

(vii) An amended test report that clearly identifies the report as an amended report on the first page, as required in 2016 TNI Standard.

(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~~CTS 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 quantitation (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3, 333-007-0410 Table 4, 333-007-0415 Table 8, and 333-007-0425 Table 9.

(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 OAR 333-007-0400 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 or negative control and laboratory control sample or positive control.

(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.

(10) If a laboratory's calculated adult use cannabinoid or CBD result exceeds 100.0 percent and the difference between the result and 100.0 percent is within the laboratory's calculated analytical measurement uncertainty, the laboratory may report the result as 100.0 percent with a qualifying statement on the certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100.0 percent is outside the calculated analytical measurement uncertainty, the calculated result ~~shall~~ must be reported without correction.

(a) The qualifying statement on the certificate of analysis ~~shall~~ must clearly state the calculated value and the laboratory's analytical measurement uncertainty.

(b) For the purposes of calculating relative percent difference (RPD) or relative standard deviation (RSD), a laboratory ~~shall~~ must use the calculated result and not the adjusted result described in this rule.

(11) A primary accredited laboratory may subcontract with accredited laboratories to perform required compliance testing. The primary accredited laboratory ~~shall~~ must issue the final report.

(a) Accredited, subcontracted laboratories ~~shall~~ must validate the results of any sample analysis and report that analysis to their client laboratory within 24 hours of completing the analytical run if the analysis results in a failed compliance test.

(b) The accredited laboratory that issues the final test report ~~shall~~ must validate and report the results of any failed sample analysis as described in section (3) of this rule.

Statutory/Other Authority: ORS 475C.544 & ORS 475C.560
Statutes/Other Implemented: ORS 475C.544 & ORS 475C.560
History:
PH 68-2024, amend filed 07/09/2024, effective 07/23/2024
PH 24-2022, amend filed 03/15/2022, effective 03/31/2022
PH 95-2021, amend filed 12/29/2021, effective 01/01/2022
PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 44-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 29-2017, amend filed 12/22/2017, effective 01/01/2018
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-064-0120

Proficiency Testing for Laboratories Accredited for Cannabis Testing

The purpose of a proficiency testing (PT) study is to provide a means for the Oregon Environmental Laboratory Accreditation Program (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 and industrial hemp-derived vapor 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 consecutive PT studies 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) A PT study is a scheduled PT study or a supplemental PT study.

(b) The proficiency testing reporting limit (PTRL) is equal to required maximum laboratory limits of quantitation (LOQs) as established in OAR 333-064-0100(12).

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

(a) Ensure that the information provided to the provider 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~~ EPA ID number listed in the ORELAP Data Input and Edit (ODIE) database; and

(C) The method and analyte codes.

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

(c) Report each quantitative field of accreditation as follows:

(A) The obtained numeric analytical result when the result is greater than or equal to the PTRL.

(B) If the PTRL is less than the laboratory's LOQ as allowed in OAR 333-064-0110(6), the laboratory ~~shall~~ must report the analytical result without qualifying the result.

(C) One of the following when the obtained numeric analytical result is less than the PTRL:

(i) <PTRL; or

(ii) The obtained analytical result if greater than or equal to the laboratory's LOQ; or

(iii) <LOQ if the obtained analytical result is less than the laboratory's LOQ.

(D) For non-detect results, <PTRL.

(d) Report each qualitative field of accreditation according to the PT provider's instructions. Presence or absence determinations in the PT ~~shall~~ must be made following the laboratory's normal procedure.

(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 provider does not match any of the items in OAR 333-064-0120(3).

(5) For pesticide, mycotoxin ~~analysis , on or after August 1, 2024~~, and potency analyses in usable marijuana, a laboratory must use PT samples made with a usable marijuana matrix. If a usable marijuana matrix is unavailable, then a PT sample made with usable hemp matrix may be used with written permission from ORELAP. If a PT sample made with a usable hemp matrix is used for accreditation of potency analysis, then the PT provider must prepare the sample in usable hemp material itself and may not provide a separate spiking solution with the sample.

(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 reported according to these rules and evaluated by the PT provider and ORELAP as acceptable.

Statutory/Other Authority: ORS 475C.544
Statutes/Other Implemented: ORS 475C.544
History:
PH 68-2024, amend filed 07/09/2024, effective 07/23/2024
PH 46-2022, minor correction filed 04/26/2022, effective 04/26/2022
PH 95-2021, amend filed 12/29/2021, effective 01/01/2022
PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 65-2020, temporary amend filed 09/24/2020, effective 09/24/2020 through 03/22/2021
PH 45-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 282-2018, adopt filed 12/20/2018, effective 01/01/2019

333-064-0140
Psilocybin Products Sampling Procedures and Testing

(1) For purposes of this rule the definitions in OAR 333-333-1010 apply unless the context indicates otherwise.

(2) Sampling.

(a) A laboratory must have and follow psilocybin products sampling policies and procedures, accredited by the Oregon Environmental Laboratory Accreditation Program (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 333, and any applicable TNI Standards.

(C) Require chain of custody procedures consistent with the TNI Standards.

(D) Are appropriate to the matrix being sampled.

(E) Are consistent with OAR 333-333-7100 and the ORELAP sampling protocol, ORELAP-SOP-004 Rev 1.0, approved by the accrediting body and incorporated by reference.

(F) Ensure that only the finished psilocybin product is sampled if testing the finished product is required under OAR 333-333-7100.

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

(b) Sampling policies and procedures must be accredited by ORELAP prior to any psilocybin product 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 manufacturer required to comply with Psilocybin Tracking System (PTS) tracking under ORS 475A.400, record the sampling and transfer information in the tracking system, as required by the Oregon Health Authority (Authority).

(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 and duplicate sample that have an unequivocal link to the laboratory analysis identification.

(C) Assign a unique identification number for the test batch in accordance with OAR 333-333-7110 and TNI 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 whole fungi ~~shall~~ must be combined into a composite sample and homogenized prior to testing.

(B) Sample increments collected from the same batch of homogenized fungi, psilocybin extract, or edibles ~~shall~~ must be combined into a composite sample.

(i) Increments from a primary sample must be combined into a single composite sample.

(ii) Increments from a duplicate sample must be combined into a composite sample separate from the primary sample composite sample.

(C) Prior to any testing or subsampling, each composite sample must undergo the laboratory's homogenization process.

(D) If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis.

(3) Compliance testing validity.

(a) When testing a sample for the required chemistry compliance tests as described in OAR 333-333-7040 and 333-333-7050, a laboratory ~~shall~~ must comply with additional method validation as follows:

(A) Run a method blank in accordance with TNI Standard requirements to demonstrate the procedure is free of contaminants at or above the limit of quantitation.

(B) Run a laboratory control sample (LCS) in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the LCS means percent recovery for all regulated analytes ~~are~~ must be within the limits specified in Exhibit D, Table 1.

(C) Calculate a measure of precision within each analytical batch. This may be done by analyzing an analytical duplicate sample or a laboratory control sample duplicate (LCSD) and calculating the relative percent difference (RPD). An analytical duplicate sample is prepared from a second aliquot of material from the same sample to determine variability of measurements within the laboratory.

(D) Run an initial calibration verification (ICV) for each initial calibration in accordance with TNI Standard requirements. Acceptable performance of the ICV means percent recovery for all regulated analytes must be within the limits specified in Exhibit D, Table 1.

(E) Run continuing calibration verification (CCV) in accordance with TNI Standard requirements. Acceptable performance of a CCV means percent recovery for all regulated analytes must be within the limits specified in Exhibit D, Table 1.

(b) When performing a speciation test as described in OAR-333-333-7030, a laboratory ~~shall~~ must use any DNA-based approach that has been validated to show acceptable inclusivity, exclusivity, and probability of detection (POD). A laboratory ~~shall~~ must comply with additional method validation as follows:

(A) The laboratory must perform initial method validation to include inclusivity and exclusivity testing using whole tissue or cultured organisms. This is to show the laboratory has proficiency with the DNA extraction, replication, and detection processes and can demonstrate the ability to differentiate between the target organism and other organisms that may be found in samples. Nothing in these rules prohibits testing laboratories from possessing *Psilocybe cubensis* for purposes of method validation and testing.

(B) Run a negative control to show laboratory reagents and equipment are not causing false positives.

(C) Run a positive control with each batch to show acceptable performance of the method. Acceptable performance means detection of target DNA sequences in the positive control that has been spiked with *Psilocybe cubensis* genetic material.

(D) Demonstrate acceptable performance as described in the manufacturer's instructions of an internal amplification control (IAC) in each sample analyzed by a polymerase chain reaction (PCR) method. In the case of a positive result for *Psilocybe cubensis* in a sample with an unacceptable performance of the IAC, follow the manufacturer's instructions on interpretation of acceptability.

(4) Compliance testing results ~~should~~ must not be adjusted for percent moisture, or on any other basis except to account for extraction and dilution during laboratory preparation.

(5) Calculating RPD and relative standard deviation (RSD~~.~~).

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

Relative Percent Difference

%RPD=|(sample–duplicate)|/((sample+duplicate)/2) * 100

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

Standard Deviation

S= √(∑((xi–x)^2)/(n–1))

Relative Standard Deviation

%RSD= (S/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 Limit of Quantitation (LOQ) the absolute value of the LOQ is used in the equation.

(6) A laboratory must provide any pesticide test result to the Authority upon its request.

(7) A laboratory performing tests for a manufacturer required to use PTS under ORS 475A.400 must enter any information required by the Authority in PTS.

(8) A laboratory performing tests for a manufacturer must comply with the documentation requirements in OAR 333-333-7100 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.

(9) The Authority may, in its discretion, permit a laboratory to deviate from TNI Standards in order to comply with OAR 333-333-7020 to 333-333-7150 and these rules based on the state's needs. Permission to deviate from TNI Standards must be in writing from the Authority.

(10) A laboratory must be able to demonstrate that its limit of quantitation (LOQ) for compliance testing is less than or equal to one-half of any action level established in OAR 333-333-7050.

(11) When performing calculations, a laboratory may not round any values during intermediate steps of a calculation. Rounding may only occur after all calculation steps have been completed.

(12) A laboratory is prohibited from the following actions during testing:

(a) fabricating, falsifying, or misrepresenting data, including but not limited to creating data for an analysis that was not performed;

(b) unwarranted manipulation of samples or analytical conditions, including unjustified dilution of samples or changing the instrument conditions for sample analysis from the conditions used for standard analysis;

(c) unwarranted manipulation of software, including forcing calibration or QC data to meet acceptance criteria, removing software operational codes indicating analyst manipulation of results, changing parameters to avoid displaying appropriate qualifiers, inappropriately subtracting background, or improperly manipulating the chromatographic baseline;

(d) turning off, or otherwise disabling, electronic instrument audit tracking functions;

(e) misrepresenting or misreporting quality control samples, including representing spiked samples as being digested or extracted when a digestion or extraction was not performed;

(f) substituting previously generated analysis for a non-compliance calibration or quality control analysis;

(g) failing to prepare or analyze method blanks (MB), matrix spikes, and laboratory control samples (LCS) in the same manner that samples are prepared or analyzed;

(h) inappropriately preparing and analyzing quality control samples;

(i) deleting or failing to record quality control data outside acceptance criteria to conceal the fact that calibration or other quality control analysis were outside acceptance criteria;

(j) performing improper manual integrations;

(k) concealing a known analytical or sample problem;

(l) removing failed quality control analysis from the record of an analytical sequence;

(m) excluding known quality control failures from the test report;

(n) observing out-of-compliance equipment conditions, then adjusting the equipment into compliance and recording only the compliant observation;

(o) performing repeated or additional testing for the purpose of achieving a preferred result; and

(q) performing repeated or additional testing for the purpose of preventing the sample from failing for an action limit described in:

(A) Speciation testing in accordance with OAR 333-333-7030;

(B) Potency testing in accordance with OAR 333-333-7040;

(C) Solvent testing in accordance with OAR 333-333-7050;

(D) Pesticide testing in accordance with OAR 333-333-7060;

(E) Contaminant testing in accordance with OAR 333-333-7070;

(F) Heavy metals testing in accordance with OAR 333-333-7080; and

(H) Failed test samples in accordance with OAR 333-333-7120.

(13~~1~~) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a manufacturer may use methods not approved by the Authority, but the laboratory may not identify those test results as accredited results.

(a) Accredited laboratories may not receive psilocybin product from a source that is not licensed under ORS 475A.290.

(b) Notwithstanding subsection (11)(a), it is not a violation of these rules for an accredited laboratory to receive materials containing psilocybin for purposes of establishing instrument calibrations or validating laboratory processes necessary for testing required under ORS 475A.590 from the following entities:

(A) Providers of certified reference materials;

(B) Approved or accredited providers of proficiency tests;

(C) The Oregon State Reference Laboratory or any agent acting in an official capacity for the Authority or the Oregon Department of Agriculture; or

(D) Individuals providing material that is not tracked in PTS for the exclusive purpose of laboratory method development.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 475A.590 & 475A.606
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 475A.590 &

475A.606

History:

PH 68-2024, amend filed 07/09/2024, effective 07/23/2024

PH 207-2022, adopt filed 12/27/2022, effective 12/27/2022

333-064-0150

Reporting Psilocybin Products Test Results

(1) For purposes of this rule the definitions in OAR 333-333-1010 apply unless the context indicates otherwise.

(2) A laboratory must ensure that test report ~~must~~ clearly identify for the manufacturer:

(a) Whether a sample has exceeded an action limit for an analyte in OAR 333-333-7050, or has otherwise failed a test as described in OAR 333-333-7030 and 333-333-7040.

(b) The batch unique identification number required under OAR 333-333-7090 and the test batch number associated with the samples tested, as required by OAR 333-333-7110.

(c) Identification of the test as a compliance test or a quality control or research and development test. If the test is not for compliance, the report ~~shall~~ must indicate clearly on the first page the testing was for quality control or research and development.

(d) If applicable, a statement that the test was done on a sample from a remediated psilocybin product.

(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 333-333-7030, 333-333-7040, and 333-333-7050, whether or not the laboratory is reanalyzing the sample under OAR 333-333-7120, into Product Tracking System (PTS) if performing testing for a manufacturer who is subject to PTS tracking under OAR chapter 333, division 333.

(4) If the laboratory discovers that an error has occurred after reporting a result to a manufacturer or into PTS, an amended report ~~shall~~ must be generated and communicated to the manufacturer. The laboratory ~~shall~~ must ensure that results entered into the PTS are accurate and updated if necessary to reflect the amended report. The laboratory ~~shall~~ must ensure that the amended report, communication, and updates to PTS as described in this rule are completed ~~within 48 hours~~11:59 a.m. the following day of ~~learning of~~ discovering the error.

(5) The laboratory must report all test results required under OAR 333-333-7030, 333-333-7040, and 333-333-7050 that have not been reported under section (3) of this rule into PTS

if performing testing for a manufacturer who is subject to PTS tracking under OAR chapter 333, division 333.

(6) Each potency testing report ~~shall~~ must include the results for psilocybin analyte and psilocin analyte expressed in mg/g as well as Total ~~Potential Psilocin~~Psilocybin Equivalent in accordance with OAR-333-333-7040.

(a) Total ~~Potential Psilocin~~Psilocybin Equivalent must be calculated as follows:

mg/g Total ~~Potential Psilocin~~Psilocybin Equivalent = 1.4 * mg/g psilocin analyte + ~~0.719 *~~ mg/g psilocybin analyte.

(b) Potency results for whole fungi ~~shall~~ must be reported as the calculated values for psilocybin analyte, psilocin analyte, and Total ~~Potential Psilocin~~Psilocybin Equivalent as determined in the composite sample.

(c) Potency results for homogenized fungi, psilocybin extract, or edibles ~~shall~~ must be reported as the calculated values for psilocybin analyte, psilocin analyte, and Total ~~Potential Psilocin~~Psilocybin Equivalent as determined in the primary composite sample.

(7) Each solvent testing report ~~shall~~ must include the results for the solvent used by the manufacturer in accordance with OAR 333-333-7050.

(8) Each speciation testing report ~~shall~~ must indicate if the batch was positively identified as *Psilocybe cubensis*.

(9) A laboratory must determine and include on each test report its limit of quantitation (LOQ) and action level for each analyte listed in OAR 333-333-7040 and 333-333-7050.

(10) 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 and the positive and negative controls in speciation testing.

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

(c) The report must clearly identify any analytes associated with quality control results outside of the acceptance limits defined in OAR 333-064-0140 Exhibit D, in accordance with TNI Standards. The quality control results are the method blank (MB), laboratory control sample (LCS), initial calibration verification (ICV), and continuing calibration verification (CCV).

(d) Quantitative quality control results must be in percent recovery.

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

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

(13) If a laboratory's calculated potency result exceeds 100.0 percent or 1000.0 mg/g and the difference between the result and 100.0 percent or 1000.0 mg/g is within the laboratory's calculated analytical measurement uncertainty, the laboratory may report the result as 100.0 percent or 1000.0 mg/g with a qualifying statement on the certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100.0 percent or 1000.0 mg/g is outside the calculated analytical measurement uncertainty, the calculated result ~~shall~~ must be reported without correction.

(a) The qualifying statement on the certificate of analysis must clearly state the calculated value and the laboratory's analytical measurement uncertainty.

(b) For the purposes of calculating RPD or RSD, a laboratory must use the calculated result and not the adjusted result described in this rule.

(14) A primary accredited laboratory may subcontract with accredited laboratories to perform required compliance testing. The primary accredited laboratory must issue the final report.

(a) Accredited, subcontracted laboratories must validate the results of any sample analysis and report that analysis to their client laboratory within 24 hours of completing the analytical run if the analysis results in a failed compliance test.

(b) The accredited laboratory that issues the final test report must validate and report the results of any failed sample analysis as described in section (3) of this rule.

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 475A.590 & 475A.606
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 475A.590 & 475A.606
History:
PH 207-2022, adopt filed 12/27/2022, effective 12/27/2022