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FILING CAPTION: Oregon Environmental Laboratory Accreditation Program (ORELAP) psilocybin accreditation rules

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RULES:
333-064-0005, 333-064-0010, 333-064-0025, 333-064-0035, 333-064-0050, 333-064-0055, 333-064-0060, 333-064-0140, 333-064-0150, 333-064-0160

AMEND: 333-064-0005

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0005:
The rule is amended to include psilocybin testing.

CHANGES TO RULE:

333-064-0005
Purpose ¶

(1) These rules are for the ~~purpose of i~~following purposes:¶
(a) Implementing Oregon Revised Statutes (ORS) 438.605 to 438.620, 448.280 and the Oregon Drinking Water Quality Act of 1981. ORS 438.610 states that the Oregon Health Authority shall, by adopting standards in concurrence with the accrediting body, implement an environmental laboratory accreditation program hereafter referred to as the Oregon Environmental Laboratory Accreditation Program (ORELAP). ~~These rules e~~¶
(b) Establish requirements for the accreditation of laboratories analyzing samples under the guidance of the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), the Resource, Conservation and Recovery Act (RCRA)~~ and~~, cannabis testing under ORS 475~~B~~C.55~~4~~0 to 475~~B.590. Testing of water samples under ORS 448.150, Oregon's Drinking Water Quality Act, must be conducted by an ORELAP accredited laborator~~C.586, and psilocybin testing under ORS 475A.590 to 475A.622. ¶
(2) The following must be done by an ORELAP accredited laboratory:¶
(a) Testing of water samples under ORS 448.150, Oregon's Drinking Water Quality Act.¶
(b) Testing and sampling of cannabis under ORS 475C.540 to 475C.586, except with written permission from the Authority or Commission.¶
(c) Testing and sampling of psilocybin products under ORS 475A.590 to 475A.622, except with written permission from the Authority.
Statutory/Other Authority: ORS 448.150~~(1)~~, 448.131, 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475~~B.565~~C.544, 475C.560, 475A.590, 475A.606

Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475~~B.565~~C.544, 475C.560, 475A.590, 475A.606

AMEND: 333-064-0010

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0010:

The rule is amended to apply to laboratories seeking accreditation for or performing psilocybin sampling and testing.

CHANGES TO RULE:

333-064-0010
Scope ¶

(1) These rules apply to:¶
(a) Laboratories seeking accreditation to perform environmental or agricultural laboratory testing;¶
(b) Laboratories seeking accreditation to perform sampling and laboratory testing of marijuana items and industrial hemp-derived vapor items as required by ORS 475~~B~~C.56~~5~~0;¶
(c) Laboratories seeking accreditation to perform sampling and laboratory testing of psilocybin products as required by ORS 475A.606; and¶
(~~c~~d) Accredited laboratories performing:¶
(A) Environmental or agricultural testing;~~ or~~¶
(B) Sampling and testing of marijuana items and industrial hemp-derived vapor items; or¶
(C) Sampling and testing of psilocybin products.¶
(2) Accreditation as described in these rules is required for all laboratories reporting drinking water analysis results to the Oregon Health Authority except for Oregon Department of Agriculture Laboratory, Oregon Department of Environmental Quality Laboratory and the Oregon State Public Health Laboratory which must be certified by the United States Environmental Protection Agency for drinking water analysis.¶
(3) Accreditation as described in these rules is required for all Oregon laboratories sampling and testing marijuana items and industrial hemp-derived vapor items.¶
(4) Accreditation as described in these rules is required for all Oregon laboratories sampling and testing psilocybin products.
Statutory/Other Authority: ORS 448.150, 448.131, 448.280, 438.605, 438.610, 438.615, 438.620, 475~~B~~C.5~~6~~544, 475~~B~~C.5~~55~~60, 475A.590, 475A.606
Statutes/Other Implemented: ORS 448.280, 438.605, 438.610, 438.615, 438.620, 475~~B~~C.5~~6~~544, 475~~B~~C.5~~55~~60, 475A.590, 475A.606

AMEND: 333-064-0025

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0025:

The definitions have been added for: “Psilocin”, “Psilocybin”, “Psilocybin product”, “Psilocybin Tracking System”, “Total Potential Psilocin”, and “Whole fungi”.

The following definitions have been amended: “Batch” to include a batch of psilocybin product, “Biological tissue” to include both cannabis tissues and psilocybin-containing fungal tissues, and “Solids” to include psilocybin products with the exception of psilocybin-containing tissue.

CHANGES TO RULE:

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~~, this term means~~:¶
(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.¶
(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) "Cannabis" has the meaning given that term in OAR 333-007-0310.¶
(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.¶
(10) "Cannabis Tracking System" or "CTS" has the meaning given that term in OAR 333-007-0310.¶
(11) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.¶
(12) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-85-2.¶
(13) "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.¶
(14) "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.¶
(15) "Commission" means the Oregon Liquor and Cannabis Commission.¶

(16) "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.¶
(17) "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.¶
(18) "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.¶
(19) "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.¶
(20) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.¶
(21) "Finished cannabinoid concentrate or extract" has the meaning given that term in OAR 333-007-0310.¶
(22) "Finished cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶
(23) "Finished inhalable cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶
(24) "Industrial hemp-derived vapor item" has the meaning given that term in OAR 333-007-0310.¶
(25) "Homogenization" means physically manipulating a sample to make the sample's material uniform in composition and properties throughout, including but not limited to reducing particle size to a fine uniform powder for solid materials or combining all layers or phases of a liquid or semi-solid sample into a uniform substance.¶
(26) "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.¶
(27) "Marijuana item" has the meaning given that term in OAR 333-007-0310.¶
(28) "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.¶
(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.¶
(30) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.¶
(31) "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.¶
(32) "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.¶
(33) "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.¶
(34) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.¶
(35) "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.¶
(36) "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.¶
(37) "Psilocin analyte" means 4-hydroxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-53-6.¶

(38) "Psilocybin analyte" means 4-phosphoryloxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-52-5.¶
(39) "Psilocybin product" has the meaning given that term in OAR 333-333-1010.¶
(40) "Psilocybin Tracking System" or "PTS" has the meaning given that term in OAR 333-333-1010.¶
(41) "Public water system" means a water system as defined in OAR 333-061-0010.¶
(~~38~~42) "Quality ~~M~~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.¶
(4~~3~~9) "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.¶
(~~40~~4) "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.¶
(~~41~~5) "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.¶
(~~42~~6) "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.¶
(~~43~~7) "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.¶
(~~44~~8) "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 ~~shall be included in this matrix as solids.~~ ¶
(b) Psilocybin products as defined in OAR 333-333-1010 with the exception of dried fruiting bodies and hyphae.¶
(~~45~~9) "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.¶
(~~46~~50) "Total Potential Psilocin" means the sum of the psilocin analyte concentration and 0.719 times the psilocybin analyte concentration. This number is the maximum theoretical concentration of psilocin in the sample.¶
(51) "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.¶
(~~47~~52) "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¶
(~~48~~53) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-01~~2~~60.¶
(5~~4~~9) "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.¶
(5~~0~~5) "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.¶
(56) "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

AMEND: 333-064-0035

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0035:

Subsection (4)(c) has been updated to include the division 64 rules as requirements for Proficiency Testing (PT) samples. This is because the TNI Standard does not include reference to either cannabis or psilocybin PT samples.

CHANGES TO RULE:

333-064-0035
Approval Requirements ¶

(1) This rule and the TNI Standards describe the procedure for obtaining and maintaining accreditation.¶
(2) ORELAP accreditation can be granted, denied, suspended, or revoked in total or in part as described in the TNI Standards.¶
(a) Reasons to deny an initial application shall include, but are not limited to:¶
(A) Failure to submit a completed application;¶
(B) Failure to pay fees;¶
(C) Failure of laboratory staff to meet the personnel qualifications of education, training, and experience as required by the TNI Standards;¶
(D) Failure to successfully analyze and report PT samples as required by the TNI Standards and these rules;¶
(E) Failure to respond to an assessment report from an on-site assessment with a corrective action report within 30 calendar days, or failure to respond to deficiencies identified in the first corrective action report review within 30 calendar days, as required by the TNI Standards;¶
(F) Failure to implement the corrective actions detailed in the corrective action report within the agreed upon time frame;¶
(G) Failure to implement a quality system as defined in the TNI Standards;¶
(H) Failure to pass required on-site assessments;¶
(I) Misrepresentation of any fact pertinent to receiving or maintaining accreditation; or¶
(J) Denial of entry during the laboratory's normal business hours for an on-site assessment.¶
(b) Reasons for suspension or revocation in total or in part shall include but are not limited to:¶
(A) If the accreditation body finds, during the on-site assessment, that the public interest, safety or welfare imperatively requires emergency action;¶
(B) Failure to complete proficiency testing studies as required by the TNI Standards and these rules;¶
(C) Failure to notify the accreditation body of any changes in key accreditation criteria defined in the TNI Standards within 35 calendar days of the effective change, including:¶
(i) General features of the laboratory, including corporate entity, name, addresses, legal status, technical directors and quality managers, and technical resources;¶
(ii) General information concerning the laboratory such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s) to be covered by the scope of accreditation;¶
(D) Failure to maintain a quality system as required by the TNI Standards;¶
(E) Failure of the laboratory to employ staff that meets qualifications for education, training, and experience as required by the TNI Standards;¶
(F) Misrepresentation of any fact pertinent to receiving or maintaining accreditation;¶
(G) Denial of entry to an accreditation body's assessment team during the laboratory's normal business hours for the purpose of conducting an on-site assessment;¶
(H) Failure to pass an on-site assessment conducted by an accreditation body;¶
(I) Failure to respond to an assessment report from an on-site assessment with a corrective action report within 30 calendar days, or failure to respond to deficiencies identified in the first corrective action report review within 30 calendar days, as required by the TNI Standards;¶
(J) Failure to implement the corrective actions detailed in the corrective action report within the agreed upon time frame; or¶
(K) Failure to pay fees.¶
(3) In no case shall a laboratory be accredited that does not comply with the TNI Standards as specified in this rule.¶
(4) The elements for accreditation shall include but are not restricted to:¶
(a) Application for accreditation:¶
(A) ORELAP will make online, electronic applications available to all laboratories requesting an application.¶
(B) The laboratory must request ORELAP accreditation by completing and submitting to ORELAP an acceptable

application that includes all elements as required by the TNI Standards. For primary accreditation this includes a completed application with all required documents. For secondary accreditation this includes a completed application with all of the required documents plus proof of accreditation from a primary accrediting body.¶
(b) ~~L~~The laboratory's participation in a biennial on-site assessment(s) as required by the TNI Standards. Environmental testing laboratories seeking initial, primary ORELAP accreditation shall not be granted accreditation prior to an acceptable on-site assessment;¶
(c) ~~L~~The laboratory's participation in proficiency testing (PT) and the obtaining of acceptable PT results according to the TNI Standards and these rules;¶
(d) A quality manual (QM) that includes all elements as set forth in the TNI Standards;¶
(e) Laboratory staff members that meet the TNI Standards for training and experience for their responsibilities within the ~~environmental~~ laboratory;¶
(f) Creation and retention of all records pertaining to samples and analyses, including chain of custody documents, log books, work sheets, raw data, calculations, quality assurance data, and reports according to TNI Standards; and¶
(g) ~~L~~The laboratory's full payment of all appropriate fees as described in OAR 333-064-0060.
Statutory/Other Authority: ORS 448.150, 448.131, 448.280, 438.605, 438.610, 438.615, 438.620, 475~~B~~C.5~~55~~44, 475C.560, 475~~B~~A.590, 475A.606~~5~~
Statutes/Other Implemented: ORS 448.280, 438.605, 438.610, 438.615, 438.620, 475~~B~~C.5~~55~~44, 475C.560, 475~~B~~A.590, 475A.606~~5~~

AMEND: 333-064-0050

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0050:

This rule has been amended to make clear ORELAP does not accredit out-of-state laboratories for cannabis or psilocybin testing.

CHANGES TO RULE:

333-064-0050
Accreditation of Out-of-State and Mobile Category 2 Laboratories ¶

(1) ORELAP shall accredit out-of-state laboratories that are eligible for reciprocal accreditation provided:¶
(a) The laboratory is accredited by a state recognized as a NELAP accrediting body for those fields of testing (analytes, methods, matrices) in which the laboratory is requesting accreditation pursuant to this rule.¶
(b) The laboratory submits to ORELAP an acceptable application as described in OAR 333-064-0035(4).¶
(c) The laboratory pays all appropriate fees as described in OAR 333-064-0060.¶
(d) The laboratory is not requesting accreditation for cannabis or psilocybin testing.¶
(2) ORELAP may accredit out-of-state laboratories that are located in states that do not have a NELAP approved accrediting body for the fields of testing and matrices in which the laboratory desires accreditation provided that the laboratory complies with all the requirements in OAR 333-064-0035.¶
(3) ORELAP may accredit mobile category 2 laboratories that do not operate as an entity of an Oregon fixed base facility as out-of-state laboratories. Such laboratories must meet all of the requirements for out-of-state laboratories pursuant to these rules.
Statutory/Other Authority: ORS 448.150~~(1) & 448.131, 448.280(1)(b) & (2)~~, 448.280, 438.605, 438.610, 438.615, 438.620, 475C.544, 475C.560, 448.131, 475A.590, 475A.606
Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475C.544, 475C.560, 475A.590, 475A.606

AMEND: 333-064-0055

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0055:

This rule has been amended to remove the adjective “environmental” from the word “laboratories” as the rule applies to display of accreditation certificate for all ORELAP-accredited laboratories.

CHANGES TO RULE:

333-064-0055
Display of Certificate ¶

Accredited ~~environmental~~ laboratories shall post or display their most recent ORELAP accreditation certificate and their ORELAP-accredited fields of testing in a prominent place in the laboratory facility.
Statutory/Other Authority: ORS 448.150~~(1) & 448.131, 448.280(1)(b) & (2)~~, 448.280, 438.605, 438.610, 438.615, 438.620, 475C.544, 475C.560, 448.131, 475A.590, 475A.606
Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475C.544, 475C.560, 475A.590, 475A.606

AMEND: 333-064-0060

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Amend OAR 333-064-0060:

Paragraph (2)(d)(D) is amended to remove the extraneous word “Microbiology”. Paragraphs (1)(a)(E) and (2)(d)(F) are amended to include psilocybin sampling.

CHANGES TO RULE:

333-064-0060
Fee Schedule ¶

Fees will be charged to Oregon and out-of-state laboratories according to the following schedule. A mobile category 2 laboratory that operates as an entity of an Oregon fixed base facility will be considered an in-state laboratory, and one that does not operate as an entity of an Oregon fixed base facility will be considered an out-of-state laboratory. Mobile category 1 laboratories are covered under the parent fixed laboratory's accreditation and are not required to pay an additional fee. Mobile category 2 laboratories require separate accreditation and are accredited to their vehicle identification numbers (VIN).¶
(1) A non-refundable application fee must be paid for each application requesting accreditation for methods.¶
(a) For laboratories located in Oregon, one of five levels of fees, Tier 1 at $1,200, Tier 2 at $2,200, Tier 3 at $3,400, Tier 4 at $4,600, and Tier 5 at $5,800 will be charged. The Tiers will be determined by the total number of points derived from the number of fields of accreditation requested for accreditation listed in subsections (2)(a) through (c) of this rule.¶
(A) Each Basic Field of Accreditation has a multiplier of 1.¶
(B) Each Moderate Field of Accreditation has a multiplier of 3.¶
(C) Each Complex Field of Accreditation has a multiplier of 5.¶
(D) Each Advanced Technology Field of Accreditation has a multiplier of 7.¶
(E) Cannabis and Psilocybin Sampling only for application has a multiplier of 11.¶
(F) The total number of points is determined by first summing the number of fields of accreditation within each category (Basic, Moderate, Complex or Advanced Technology) and then multiplying the sums by their appropriate multiplier as given in this rule. The sum of these results determines the total number of points for each laboratory. Laboratories with a total of 1 to 10 points are to be considered Tier 1 laboratories, 11 to 25 points are Tier 2 laboratories, 26 to 40 points are Tier 3 laboratories, 41 to 55 points are Tier 4 laboratories, and 56 or more points are Tier 5 laboratories.¶
(b) For each out-of-state laboratory requesting primary or secondary accreditation through ORELAP, one of five levels of fees, Tier 1 at $3,100, Tier 2 at $4,850, Tier 3 at $6,950, Tier 4 at $9,050, and Tier 5 at $11,150 will be charged with each Tier determined according to paragraphs (1)(a)(A) through (F) of this rule.¶
(c) If a new owner acquires the laboratory and wishes the laboratory to remain accredited, the laboratory must submit a new owner application, and may be required to pay the application fee and be subject to a new on-site assessment and payment of on-site assessment fees as described in this rule.¶
(2) Upon ORELAP's review of a laboratory's application, each laboratory requesting primary accreditation through ORELAP will be charged an assessment fee as follows:¶
(a) Laboratories will be charged $200 for each of the following Basic Fields of Accreditation requested for accreditation:¶
(A) Gravimetric;¶
(B) Physical;¶
(C) Probe.¶
(b) Laboratories will be charged $600 for each of the following Moderate Fields of Accreditation requested for accreditation:¶
(A) Inorganic Atomic absorption spectrometry;¶
(B) Inorganic Atomic fluorescence spectrometry;¶
(C) Inorganic-non-metals automated colorimetric;¶
(D) Inorganic-non-metals manual colorimetric;¶
(E) Inorganic-ion chromatography (IC);¶
(F) Organic-liquid chromatography (LC);¶
(G) General microbiology including but not limited to these three: 1) Chromofluorogenic; 2) Membrane Filter and /or Heterotrophic Plate Count (HPC); and 3) Multiple Tube Fermentation/Most Probable Number (MPN) (one fee applies for all);¶
(H) Asbestos (bulk).¶

(c) Laboratories will be charged $1,000 for each of the following Complex Fields of Accreditation requested for accreditation:¶
(A) Organic - gas chromatography/mass spectrometry (GC/MS) - volatiles;¶
(B) Organic - gas chromatography/mass spectrometry (GC/MS) - extractables;¶
(C) Organic - liquid chromatography/mass spectrometry (LC/MS);¶
(D) Organic - gas chromatography (GC) volatiles, extractables;¶
(E) Inorganic - metals - inductively coupled plasma/atomic emission spectrometry (ICP/AES);¶
(F) Inorganic - metals - inductively coupled plasma/mass spectrometry (ICP/MS);¶
(G) Inorganic - ion chromatography/mass spectrometry (IC/MS);¶
(H) X-ray;¶
(I) Whole Effluent Toxicity (WET);¶
(J) Radiochemistry;¶
(K) Immunoassay;¶
(L) Asbestos - electron microscopy.¶
(d) Laboratories will be charged $1,400 for each of the following Advanced Technology Fields of Accreditation requested for accreditation:¶
(A) Organic - gas chromatography/tandem mass spectrometry (GC/MS/MS);¶
(B) Organic - high resolution gas chromatography/high resolution mass spectrometry (HiResGC/HiResMS);¶
(C) Organic - liquid chromatography/tandem mass spectrometry (LC/MS/MS);¶
(D) ~~Microbiology -~~ Polymerase chain reaction (PCR);¶
(E) Mycology and Parasitology - Filtration/Immunomagnetic Separation/Immunoflurorescence Assay microscopy (Filtration/IMS/FA);¶
(F) Cannabis or Psilocybin Sampling.¶
(e) The following additional fees will be charged to Oregon laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:¶
(A) $10 for Basic Fields of Accreditation.¶
(B) $40 for Moderate Fields of Accreditation.¶
(C) $75 for Complex Fields of Accreditation.¶
(D) $150 for Advanced Technology Fields of Accreditation.¶
(f) The following additional fees will be charged to out-of-state laboratories for each additional matrix per field of accreditation for which the laboratory has requested accreditation:¶
(A) $13 for Basic Fields of Accreditation.¶
(B) $53 for Moderate Fields of Accreditation.¶
(C) $100 for Complex Fields of Accreditation.¶
(D) $198 for Advanced Technology Fields of Accreditation.¶
(3) For purposes of section (2) of this rule the matrices are:¶
(a) Air;¶
(b) Biological tissue;¶
(c) Drinking water;¶
(d) Non-potable water; and¶
(e) Solids.¶
(4) Assessment fees must be paid before a routine on-site assessment will be performed.¶
(5) All laboratories must pay the appropriate on-site assessment fee per on-site assessment performed due to just cause according to TNI Standards.¶
(6) ORELAP may use third party assessors to provide assessment services. In this event, the laboratory will still pay the assessment fee described in this fee schedule to ORELAP. Upon the laboratory's consent to the third party assessment, ORELAP will pay the third party assessor costs.¶
(7) All out-of-state laboratories must pay all on-site assessment costs incurred by ORELAP approved assessors to perform the on-site assessment including but not limited to transportation, per diem and wages during travel. For a mobile category 2 laboratory, the travel costs are waived if it is moved to the Oregon State Public Health Laboratory for the on-site assessment, and reduced to the amount in excess of its fixed base facility when moved to the fixed base facility if both are to be assessed at the same time. The excess amount is to be determined by those fields of accreditation and matrices requested for accreditation by the mobile laboratory that have not been requested by its fixed based facility.¶
(8) Accredited laboratories requesting additions to their fields of accreditation during the accreditation period must pay:¶
(a) The difference in cost of the application fee with a minimum fee of $200;¶
(b) The difference in cost of the assessment fee.
Statutory/Other Authority: ORS 448.150, 448.131, 448.280, 438.605~~-~~, 438.62~~1~~0, ~~448.28~~38.615, 438.620,

475~~B~~C.5~~5~~44, 475C.560, 475~~B~~A.590, 475A.606~~5~~
Statutes/Other Implemented: ~~ORS 438.605 -~~448.280, 438.605, 438.610, 438.615, 438.620, 475~~B~~C.5~~5~~44, 475C.560, 475~~B~~A.590, 475A.606~~5~~

ADOPT: 333-064-0140

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Adopt OAR 333-064-0140:

This rule is adopted to describe requirements for compliance psilocybin sampling and laboratory testing. Section (2) specifies what policies and procedures must be in place for laboratories performing psilocybin product sampling. It also incorporates by reference the ORELAP sampling protocol. Section (3) describes laboratory testing requirements including quality control (QC) parameters, equations needed for calculating QC parameters, and minimum levels of test sensitivity.

CHANGES TO RULE:

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 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 PTS tracking under ORS 475A.400, record the sampling and transfer information in the tracking system, as required by the 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 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 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.¶
(iii) Prior to any testing or subsampling, each composite sample must undergo the laboratory's homogenization process.¶
(iv) 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 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 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 percent 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.¶
(b) When performing a speciation test as described in OAR-333-333-7030, a laboratory shall use any DNA-based approach that has been validated to show acceptable inclusivity, exclusivity, and probability of detection (POD). A laboratory shall 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) Show acceptable performance of an internal amplification control in each sample to indicate DNA extraction, replication, and detection occurred. ¶
(4) Compliance testing results should 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 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) 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.
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

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

ORELAP

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Protocol for Collecting Samples of Psilocybin Products

ORELAP-SOP-004 Rev 1.0

ORELAP Executive Board and Program Approval Signatures:

Lori Pillsbury, DEQ LEAD Division Administrator — Date: 12/14/2022

Patrick Luedtke, MD, MPH, Oregon State Public Health Laboratory Director — Date: 12/19/2022

Kathleen Wickman, ODA Laboratory Manager — Date: 12/19/2022

Travis Bartholomew, ORELAP Manager — Date: 12/12/2022

Sara Krepps, ORELAP QA Officer — Date: 12/12/2022

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Acknowledgements

Revision 1.0 of this document was authored by Steven Jetter, ORELAP Cannabis Policy Developer, and reviewed by Travis Bartholomew, ORELAP Manager, and the ORELAP Executive Board. Input from the Rules Advisory Committee meeting held September 12, 2022 provided additional technical content. The information and formatting in this document were based on cannabis sampling protocols originally authored by the Oregon Cannabis Sub-Committee with input from technical experts.

I. Introduction and Scope

Obtaining a representative sample from a decision unit is one of the key elements of accurate laboratory analysis. Laboratories collect representative samples by consistently using standard sampling methods and equipment, preventing contamination of the sample, and maintaining the sample identity within the batch. The laboratory must consistently use documented standard sampling practices, tools, and methods. These practices, tools, and methods must be appropriate for the matrix. If proper protocols are in place and adhered to for sample collection, the laboratory analysis of the sample should reflect the composition of the batch as a whole at the time the sampling occurred, within recognized tolerances.

Controlling cultivation or manufacturing error is the responsibility of the manufacturer of the psilocybin product. Sampling error must be controlled by the laboratory 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. Sampling bias must also be controlled by the laboratory to ensure the sample remains representative of the decision unit. Randomized increment locations, as determined by the laboratory's sampling plan, prevent intentional or unintentional sampling bias.

This protocol is for use by ORELAP-accredited laboratories performing psilocybin product sampling as defined in OAR 333-064-0140. It focuses on standard and correct sampling practices that should be reflected in a laboratory's own sampling policies and procedures

II. Records and Documentation

1. ORELAP-accredited laboratories shall maintain standard operating procedures (SOPs) that accurately reflect current sampling activities.
    a. The laboratory's SOP shall be readily accessible to all pertinent personnel.
    b. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
    c. The laboratory's SOP should use this protocol as minimum requirements and must include additional detail specific to laboratory procedures. In cases where the published method (this protocol) has been modified or where the referenced method (this protocol) is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described in the laboratory's SOP. Any changes to the laboratory's protocol, including use of a selected option, shall be documented and included on the laboratory's sampling form.
    d. All documents shall be controlled and retained in accordance with the TNI Standard as defined in 333-064-0025.

2. ORELAP-accredited laboratories shall maintain sampling plans.

a. The laboratory's sampling plans shall be made available at their location of use.
b. The laboratory's 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.
c. Any deviation from or addition to the laboratory's sampling plan must be documented in detail and shall be included in the final report. The standardized or generic sampling plans can be included in the SOP however specialized client requests or products may require additional information.
d. The laboratory's sampling plans shall document the date and time of sampling.

III. Client Sampling and Testing Requests

The laboratory must have a sampling contract with a client that includes at least the following:

1. A test order containing the information required by OAR 333-333-7020

IV. Planning

Prior to beginning the sampling procedure, the laboratory shall gather information about the type(s) of psilocybin product being sampled, the conditions under which the psilocybin product is being kept, and batch size. This information may be included in the sampling contract or test order. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-333-7100 and OAR 333-064-0140.

The testing requirements for psilocybin products are in OAR 333-333-7010 to 333-333-7080. The requirements for batch sampling and sample size are in OAR 333-333-7090 to 333-333-7110 and Section VII and Appendix 2 of this protocol. Per Authority request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan shall be designed such that any part or individual unit in the batch has an equal chance of being selected. The laboratory shall develop procedures, and implement them in the sampling plan, which achieve randomized incremental sampling. Procedures shall include how to:

1. Assign location numbers within containers and among a set of containers holding batch material.
2. Use a random number generator to determine which location to take increments from.
3. Document where each sample increment was taken from batch container(s) and the mass collected for each increment.

Samplers must take extreme care if planning to sample from multiple sites in one day to

ensure contaminants, pathogens, or organisms are not transferred between facilities. Samplers must follow any client requirements on personal protective equipment, sterilization, or sanitization when sampling at the client's facility. If the test order or sampling request includes speciation testing, sampler must ensure equipment used is free of interfering genetic material. The sampler must clean reusable sampling equipment between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.

V. Sampling Design and Plans

1. Sampling plans shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch at the time of sampling. Standardized sampling plans can be included in the laboratory's SOP however specialized client requests or products may require additional information.
2. A site-specific sampling plan that uses statistical design for each project to provide representative sampling must be generated prior to beginning the sampling procedure. The plan shall guide samplers on how to assign divisions based on the type of container holding the batch material. Container types greater than four inches deep shall have divisions assigned to the layer or layers beneath the upper portion of the container. A random number generator programmed to provide assignments based on the total number of divisions in the containers will be employed to indicate which locations increments are pulled from. 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."
3. 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 reduce error is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity. Any deviation from or addition to the sampling plan must be documented in detail and shall be maintained in the laboratory's sample records.
4. **Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the manufacturer**. 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. Sampling plans must also indicate the minimum number of sample increments required in Table 1 and Table 2 in Appendix 2 of this protocol.
5. A sampling plan must include at a minimum:
    a. Shape, size, and number of container(s) holding the batch from which sample increments will be collected;
    b. Number of sample increments to be collected;
    c. Total mass of sample needed to perform testing and approximate mass needed for each increment to ensure adequate mass;
    d. Location of where sample increments will be taken within each container

holding the batch.

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

VI. Sampling Equipment and Supplies

1. A laboratory should, at a minimum, have the following equipment and supplies for sampling:
    a. Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
    b. Tongs
    c. Corers
    d. Teri-wipes or equivalent
    e. Calibrated field balance (capable of 0.01 g measurements)
    f. Calibrated verification weights appropriate to verify accuracy of field balance
    g. Cleaning supplies – ex: solvent, bleach, 70% Ethanol
    h. Gloves (powder-free, nitrile, sterile)
    i. Mylar bags or amber or colorless glass jars that have been verified to be clean or sterile as needed (for final sample transport and storage)
    j. Desiccant packets or similar to provide moisture control if necessary

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

3. Field balance calibration verification
    a. The laboratory sampling technician shall verify the calibration of the field balance at the sampling location.
    b. When multiple sampling events occur on the same day, the balance calibration shall be verified at each sampling location.
    c. Balance calibration verifications shall be documented.

VII. Procedure for Sampling Psilocybin Products.

1. Locate the batch of psilocybin product to be sampled. The sampler **must** have access to the entire batch.
2. Check for any signs of non-uniformity within the batch and document the observations.
    a. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers
    b. During sampling, the sampler shall look for physical differences in the psilocybin product being sampled such as color, visible layers, age of whole dried fungi, relative size of items, or texture.
    c. 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 any sample drawn may not be representative for testing.
    d. The sampler shall note these anomalies in the sample collection report.
3. Review the container label information for batch number and other pertinent information. Do not sample if unique batch numbers are not available.
4. Determine the sample matrix. Psilocybin products fall into two groups for purposes of sampling and testing:
    a. Whole fungi
    b. Homogenized fungi, psilocybin extracts, or edibles.
5. Record the total batch weight and the number of containers comprising the batch. If the product is already in final packaging, record the total number of final package units.
6. Establish which tests will be performed.
7. Ensure that appropriate equipment and containers are available for the tests being performed. For residual solvent analysis, use glass containers that can be properly sealed to prevent the loss of solvent gas and minimize the headspace remaining in the sample container. If colorless glass containers are used, the container must also be enclosed in a mylar bag to protect the sample from light. For whole dried fungi, ensure sample containers contain desiccant packets to maintain product dryness during transport and storage.
8. Select the appropriate sampling tool to ensure that it reaches all portions of the batch.
    a. Sampling tools must be unused or cleaned appropriately prior to use if reusable to prevent cross-contamination of samples. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
    b. 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.
    c. Decontamination waste shall be collected and properly disposed of if not used for analysis.
    d. Where aseptic technique is required, samplers shall observe best practices to prevent microbiological contamination of samples. For an example of aseptic technique, see the FDA (2015) Aseptic Sample Guidelines (Investigations Operations Manual Subchapter 4.3.6).

9. Collect at minimum the required number of sample increments according to Table 1 and Table 2 in Appendix 2 of this protocol and the laboratory sampling plan. Approximately equal amounts of material 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 material which is not being collected. See sections below for more detail on sampling whole fungi, liquid, semi-solid, or solid sample matrices.
10. Record the number of increments collected, the mass of each increment, and the location within containers the increment was taken.
11. Once taken, seal and label the sample increments, composite sample, primary sample, or duplicate sample as applicable with the following minimum requirements:
    a. Harvest or process lot unique identification number
    b. Name of the laboratory
    c. Laboratory's unique sample identifier
    d. Sampling date and name of sampler
    e. The phrase "PRODUCT NOT TESTED" in bold capital letters no smaller than 12-point font
12. Apply a custody seal to the sample container in a manner that prevents the psilocybin product sample from being tampered with prior to testing.
13. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the TNI Standard.
14. Record the sampling event and material transfer in the psilocybin tracking system (PTS) under the manufacturer's number.

15. **Apply the following guidelines when taking whole fungi samples:**
    a. Determine the total batch weight. Per OAR 333-333-7090, harvest lots must be separated into batches weighing no larger than 1.0 kg. Do not proceed with sampling if batch weight exceeds 1.0 kg.
    b. Determine the required minimum number of increments based on Table 1 in Appendix 2 of this protocol and the laboratory's site-specific sampling plan. Additional sample increments may be collected if needed for laboratory analysis or at client request based on the statistical design in the sampling plan.
    c. Determine the minimum mass of each sample increment such that the total mass of all increments is equal to or greater than 2.0% by weight of the batch.
    d. Carefully pull sufficient mass for each increment as determined above. The combined mass of sample increments shall consist of sufficient material to perform the required laboratory methods. Increments should be approximately equivalent to each other.
    e. Each sample increment shall be taken from a randomly chosen position in the batch, as practically possible. A sample increment shall be taken from each container if possible. If more containers exist than sample increments required, sample from as many as possible to obtain a representative sample.
    f. Psilocybin analyte and psilocin analyte concentrations may vary widely between fruiting bodies in a batch. A high degree of variability may be found between young mushrooms (sometimes referred to as aborts) and older

mushrooms. It is critically important the sampler follow the randomized plan for taking sample increments while also ensuring the sampled material is representative of the batch.

g. Combine each sample increment into the composite sample and store in a mylar bag to protect sample material from light and moisture. Secure the bag or bags with tamper-proof seals.

16. **Apply the following guidelines when taking liquid samples:**
    a. If the sample increments are to be taken from a bulk container, ensure proper homogenization of the product prior to taking the sample by mixing the container thoroughly and employing any process for homogenization that the manufacturer would use to disperse the liquid material into packaging.
    b. Determine the total batch weight and the required number of increments based on Table 2 in Appendix 2 of this protocol and the site-specific sampling plan for the client.
    c. Select an appropriate sampling device for pulling bulk liquid from a container.
    d. Collect the appropriate number of sample increments.
    e. Combine all sample increments in the selected container type to form the primary sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure.
    f. Complete the same procedure with a second set of equivalent sample increments to form the duplicate sample.
17. **Apply the following guidelines when taking solid or semi-solid samples:**
    a. Determine the total batch weight. If the batch is in final product packaging, determine how many final package units there are and the total batch mass.
    b. Determine the required number of increments based on Table 2 in Appendix 2 of this protocol and the site-specific sampling plan for the client.
    c. Select an appropriate sampling device based on the batch matrix.
    d. Collect the appropriate number of sample increments.
    e. Combine all sample increments in the selected container type to form the primary sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure.
    f. Complete the same procedure with a second set of equivalent sample increments to form the duplicate sample.

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler shall complete a sampling report form for each batch sampled. Sample report forms shall include at a minimum the following information:
    a. Name and address of manufacturer including license number
    b. Psilocybin product type.
    c. Total weight of batch.
    d. Sample identification number (ID) which can be linked through documentation to the manufacturer's unique batch ID.
    e. Total number of containers sampled.

   f. Number of sample increments taken from each container.
   g. Number of sample increments combined into a primary and duplicate sample, if applicable
   h. Number of sample containers collected.
   i. Weight and location of each sample increment.
   j. Total weight sampled.
   k. Sampling plan document control ID and revision date.
   l. Sampling procedure document control ID and revision date.
   m. Description of equipment and tools used.
   n. Address where sampled.
   o. Date sampled.
   p. ORELAP laboratory identification number.
   q. Lab license number.
   r. Sampler's identification and/or signature.
   s. Name of responsible party for the batch and transport information.
   t. Receiving laboratory and types of tests required or requested.
2. A chain of custody form shall be used. The tracking manifest in the psilocybin tracking system (PTS) may function as the chain of custody so long as it includes at least the following information:
   a. Sampler's name
   b. Sampling location
   c. Unique sample ID
   d. Sampling date/time
   e. Sample mass
   f. Custody transfer signatures
   g. Custody transfer dates/times
3. If any of the above information requested on the sampling report form or chain of custody is unavailable, indicate "N/A" in the appropriate space with an explanation as to why the information is not available.
4. All sampling report forms must be signed by the sampler.

IX. Transportation and Handling of Samples

1. Transport the composite sample to the laboratory performing the analysis by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the batch sampled and the chain of custody form continues to document sample integrity. Note: Current law does not permit shipping in any form such as USPS or FedEx.
2. Containers for sample transport must be designed to protect the sample from moisture and temperature extremes and to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling is a mylar bag or amber or colorless glass jar with a PTFE-lined lid and should be appropriate for the sample matrix and the tests required. If a colorless glass jar is used, the container must also be placed in a mylar bag to protect the sample from light exposure. A tamper-proof seal is required on each sample container.
3. 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.

4. Submit the composite sample to the laboratory in its entirety. In a situation where the sample must be split for analysis by two different laboratories, for example when solvent analysis is subcontracted to another laboratory, the composite sample(s) shall be homogenized by the laboratory's approved sample homogenization process prior to subsampling. Care must be taken to maintain sample integrity during this process. This shall be reflected on the chain of custody.
5. 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.

X. Quality Assurance and Quality Control

The sampler must be prepared to collect adequate sample mass for all analyses requested by the manufacturer. 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 internal quality control samples required by the laboratory, such as laboratory duplicates or matrix spikes.

1. Sampler qualifications
    a. Basic qualifications for samplers of psilocybin products are:
        i. Physically able to perform the duties of a sampler;
        ii. No conflict of interest;
        iii. Employed by an ORELAP accredited laboratory;
        iv. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
        v. Permitted as a licensed representative under Oregon Psilocybin Services rules to transport the required quantity of psilocybin products.
    b. Required education and training for samplers:
        i. Initial training: training shall include principles, procedures, and policies of sampling. The training shall be performed by an instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel go through initial training, they are qualified to train others in their organization.
        ii. Initial field or on-the-job training: 8-hours of training on various sampling techniques.
        iii. Continuing education: periodic refresher training shall be done annually.

2. Demonstration of Capability

    a. Prior to acceptance and institution of any accredited method, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the sampling 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.

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

        i. Comparison of replicate samples within defined Relative Standard Deviation (%RSD) acceptance criteria.

        ii. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within defined Relative Percent Difference (%RPD) acceptance criteria.

    c. Thereafter, ongoing continuing demonstration of capability (CDOC) 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.

3. Field QC samples

    a. Duplicates

        i. A duplicate sample is required when sampling a batch of homogenized fungi, extract, or edible psilocybin product. The sample duplicate must be collected using the same procedure as the primary sample. Comparison of primary and duplicate potency results must be evaluated against %RPD or RSD requirements as specified in OAR 333-333-7040.

    b. Equipment blanks

        i. 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 that occur in the field during sampling. It is recommended but not required that an equipment blank is collected upon each sampling event using new or previously certified equipment to demonstrate the equipment was not a source of contamination.

ii. The equipment blank consists of an aliquot of the cleaning solution as applicable, rinsed across sample collection equipment after cleaning has taken place. If the analytes of interest are detected in the equipment rinsate, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.
iii. The equipment blank must pass the required analysis at <LOQ for cleaning validation.
iv. 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.

c. Transport blank
   i. A transport blank is **required** as part of a sampling plan that includes collection for solvent analysis.
   ii. A single transport blank must be collected and analyzed per trip regardless of the amount of sampling events during the trip and each event's samples must be linked to the acceptability of its result.
   iii. The transport blank must pass solvent analysis at <LOQ for the sampling event to be considered valid.

4. Field audits

   a. 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.

   b. 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.

   c. Required components of the field audit program:
      i. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol.

ii. Observe the sampler conducting sampling procedures.
iii. Record any deficiencies and initiate corrective action.

XI. 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)

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FDA (2015). Subchapter 4.3.6: Aseptic Sample. *In:* Investigations Operations Manual Chapter 4: Sampling. 106 pp.

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

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

Oregon Administrative Rules, *Psilocybin* Chapter 333, Division 333.

Oregon Administrative Rules, *Accreditation of Laboratories,* Chapter 333, Division 64.

ORELAP-SOP-001 Revision 4.1 *Protocol for Collecting Samples of Usable Marijuana.*

ORELAP-SOP-002 Revision 4.3 *Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items.*

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

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

Authority means Oregon Health Authority

Batch means a quantity of psilocybin product from a harvest lot or a process lot.

Chain of Custody Form means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory. (Sample tracking document)

Composite Sample means a sample composed of all sample increments taken from a batch.

Container means a sealable, hard- or soft-bodied receptacle in which a psilocybin product is placed during sampling, transport, and storage.

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

Duplicate Sample means sample increments taken in an identical manner to sample increments taken for the primary sample and representative of the same psilocybin product being sampled that is prepared and analyzed separately from the primary sample.

Edible psilocybin product means psilocybin extract or homogenized fungi that has been incorporated into a food item or potable beverage.

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.

Extract means a product made by separating psilocybin from fungi by using a solvent.

Fundamental Sampling Error (FSE) means a measure of the 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 a psilocybin product has uniform composition and properties throughout each batch or process lot.

Homogenized fungi means dried fruiting bodies or mycelium that have been mixed by powdering or other techniques which uniformly distribute psilocybin throughout the product.

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 475A.606 to sample or

conduct tests on psilocybin products and licensed by the Authority under ORS475A.594.

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

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

Process Lot has the meaning given that term in OAR 333-333-1010.

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

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

Psilocybin product has the meaning given that term in OAR 333-333-1010.

Relative Percent Difference means the comparison of two quantities while taking into account the size of what is being compared. If the final result (i.e., psilocin analyte) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

$$\%RPD = \frac{|(sample - duplicate)|}{(sample + duplicate)/2}\ x\ 100$$

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 the final result (i.e., psilocin analyte) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

Standard Deviation

$$S = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})^2}{(n-1)}}$$

Relative Standard Deviation

$$\%RSD = \frac{S}{\bar{x}}\ x\ 100$$

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

$\bar{x}$ = mean of n values.

Representative Sample means a sample obtained according to an incremental 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 psilocybin product collected by laboratory personnel from a manufacturer for the purpose of laboratory testing.

Sample Increment means an amount of a psilocybin product collected by laboratory personnel from a manufacturer that may be combined into a sample for purposes of testing.

Sample Quality Criteria (SQC) means a series of statements that clarify a sampling program's 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 in such a way as to provide authenticity or integrity of the sample.

Sterile means the removal of all living microorganisms and other pathogens from a psilocybin product by treating it with approved chemicals or subjecting it to high heat.

TNI Standard means the TNI Environmental Laboratory Standard as defined in OAR 333-064-0025.

Transport Blank means a sample of analyte-free media which has been carried into the field and returned to the laboratory and is used to demonstrate transportation of samples did not add volatile contamination in solvent analysis.

Whole fungi means dried fruiting bodies or mycelium of *Psilocybe cubensis*, or portions thereof, that have not been homogenized.

Appendix 2 – Sample size and increments

Per OAR 333-333-7100, the sample size must be sufficient to complete all analyses required.

The required sample increments for a given batch of psilocybin products varies depending upon the product type and the size of the batch. Taking more sample increments than required is encouraged and will improve representativeness of the sample in relation to the batch.

Whole fungi:

1. The number of required sample increments for a batch are based on the size of the batch. See Table 1, below.
2. Each increment shall be taken from the batch according to the random and representative sampling approach described in this protocol and in the laboratory's sampling plan.
3. Record the mass and location within the batch for each increment.
4. The total mass of all increments must be equal to or greater than 2.0% of the batch mass.
5. Each increment is placed into a mylar bag to form the composite sample. After homogenization at the laboratory, the composite sample is prepared and analyzed for required tests.

Table 1 – Sample increment requirements based on size of dried whole fungi batch.

Batch Weight		Sample Increments Required
Ounces	Grams	
0-3.52	0-100	7
3.53-10.58	100.1-300	8
10.59-21.16	300.1-600	9
21.17-35.27	600.1-1000	10

Homogenized fungi, psilocybin extracts, or edibles:

1. The number of required increments for a batch are based on the size of the batch. See Table 2, below.
2. The mass of each increment is not specified, but the combined mass of all increments must be sufficient to complete all required analyses, laboratory QC, and re-analyses.
3. The specified number of increments are taken from the batch following the random and representative sampling approach described in this protocol and in the laboratory's sampling plan.
4. The mass and location within the batch for each increment is recorded and each increment is placed into the selected sample container. This is the primary sample.
5. An equivalent number of increments sampled using the same random and

representative procedure are combined into the duplicate sample.

6. The primary and duplicate samples are put in separate containers and are prepared and analyzed separately.

Table 2 – Sample increment requirements based on size of psilocybin extract, edible, or homogenized fungi batch.

Batch Weight		Sample Increments Required	
Pounds	Kilograms	Primary	Duplicate
0-3.31	0-1.50	3	3
3.32-6.61	1.51-3.00	4	4
6.62-13.23	3.01-6.00	5	5
13.24 +	6.01 +	6	6

Appendix 3 – Document history

Table 3 – Revision history of this protocol

Revision	Date	Summary of changes made, and initials of editor
1.0	12/9/2022	Initial draft. STJ 07/22/2022. Incorporated changes suggested during RAC convened on 9/12/2022. STJ 10/3/2022. Incorporated editorial change raised during ORELAP executive team review. TJB/STJ 12/12/2022.

OAR 333-064-0140, Exhibit D

Table 1 – Accuracy requirements for laboratory control samples (LCS).

Test	Analyte	LCS Limits (%R)
Potency in accordance with OAR 333-333-7040	Psilocybin analyte	70 - 130
	Psilocin analyte	70 - 130
Solvent testing in accordance with OAR 333-333-7050	Methanol	60 - 120
	Acetic acid	60 - 120

ADOPT: 333-064-0150

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Adopt OAR 333-064-0150:

This rule is adopted to outline requirements for laboratory reporting of compliance testing. The rule specifies the timing of reporting testing results into the Psilocybin Tracking System (PTS) and the contents of reports.

CHANGES TO RULE:

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 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 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 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 be generated and communicated to the manufacturer. The laboratory shall ensure that results entered into the PTS are accurate and updated if necessary to reflect the amended report. The laboratory shall ensure that the amended report, communication, and updates to PTS as described in this rule are completed within 48 hours of learning of 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 include the results for psilocybin analyte and psilocin analyte expressed in mg/g as well as Total Potential Psilocin in accordance with OAR-333-333-7040.¶
(a) Total Potential Psilocin must be calculated as follows:¶
mg/g Total Potential Psilocin = mg/g psilocin analyte + 0.719 * mg/g psilocybin analyte.¶
(b) Potency results for whole fungi shall be reported as the calculated values for psilocybin analyte, psilocin analyte, and Total Potential Psilocin as determined in the composite sample. ¶
(c) Potency results for homogenized fungi, psilocybin extract, or edibles shall be reported as the calculated values for psilocybin analyte, psilocin analyte, and Total Potential Psilocin as determined in the primary composite sample. ¶
(7) Each solvent testing report shall include the results for the solvent used by the manufacturer in accordance with OAR 333-333-7050.¶
(8) Each speciation testing report shall 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.¶
(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 percent or 1000mg/g and the difference between the result and 100 percent or 1000mg/g is within the laboratory's calculated analytical uncertainty, the laboratory

may report the result as 100 percent or 1000mg/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 percent or 1000mg/g is outside the calculated analytical uncertainty, the calculated result shall be reported without correction.¶
(a) The qualifying statement on the certificate of analysis must clearly state the calculated value and the laboratory's analytical 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

ADOPT: 333-064-0160

NOTICE FILED DATE: 10/28/2022

RULE SUMMARY: Adopt OAR 333-064-0160:

This rule is adopted to outline actions ORELAP may take against a laboratory as a result of violating these rules.

CHANGES TO RULE:

333-064-0160
Psilocybin Laboratory Violations and Enforcement
(1) In addition to any violation of these rules, it is a violation for a laboratory accredited for psilocybin product 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 333-333-7020 or 333-333-7110.¶
(c) Fail to comply with any applicable TNI standard.¶
(d) Report false or misleading information to the Authority or to a client.¶
(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 psilocybin product sampling or analysis; and¶
(b) Deny, suspend or revoke accreditation of a laboratory accredited for sampling or analyzing psilocybin products.¶
(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 438.605, 438.610, 438.615, 438.620, 475A.590, 475A.606, 475A.618
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 475A.590, 475A.606, 475A.618