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

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RULES:
333-064-0025, 333-064-0035, 333-064-0045, 333-064-0060, 333-064-0065, 333-064-0100

AMEND: 333-064-0025

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0025 “Definitions”: Update to the definition of “TNI Standards” from the 2009 NELAC Institute revision to the 2016 NELAC Institute revision. This change will allow ORELAP to adopt the most recent requirements for laboratories to ensure high quality testing.

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) "Air" as a matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.¶
(3) "Authority" means the Oregon Health Authority.¶
(4) "Biological tissue" as a matrix means samples of biological tissue, excluding those of human origin.¶
(5) "Cannabis sampling" means an activity related to obtaining a representative sample of a marijuana item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.¶
(6) "Cannabis Tracking System" or "CTS" means the Oregon Liquor Control Commission's system for tracking the transfer of marijuana items and other information as authorized by ORS 475B.177.¶
(7) "Clean Air Act (CAA)" means the enabling legislation, 42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399, that empowers the EPA to

promulgate air quality standards, monitor and enforce them.¶
(8) "Clean Water Act (CWA)" means the enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816 that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.¶
(9) "Drinking water" as a matrix means samples of presumed potable water and source water, which are analyzed for possible contaminants under the guidance of the Safe Drinking Water Act.¶
(10) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.¶
(11) "Finished cannabinoid concentrate or extract" means a cannabinoid concentrate or extract that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.¶
(12) "Finished cannabinoid product" means a cannabinoid product that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids. ¶
(13) "Laboratory" means a fixed location or mobile facility that collects or analyzes samples in a controlled and scientific manner with the appropriate equipment and instruments required by accredited sampling and testing methods.¶
(14) "Marijuana item" has the meaning given that term in ORS 475B.550.¶
(15) "Mobile Category 1 Laboratory" means any facility, deployed for no more than six consecutive months and no more than six months during a calendar year, that:¶
(a) Analyzes samples utilizing the staff and equipment from the parent fixed laboratory;¶
(b) Operates under the quality system of its parent fixed laboratory;¶
(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and¶
(d) May operate under the fixed laboratory's accreditation.¶
(16) "Mobile Category 2 Laboratory" means any facility that:¶
(a) Analyzes samples;¶
(b) Operates under its own quality system;¶
(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and¶
(d) Issues the final reports or is a mobile laboratory operating with a fixed laboratory's quality system, but is deployed for more than six consecutive months or more than six months in a calendar year.¶
(17) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.¶
(18) "NELAP approved accrediting body" means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the TNI Standards.¶
(19) "Non-potable water" as a matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.¶
(20) "On-site assessment" means an on-site visit to the laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards.¶
(21) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.¶
(22) "Primary accreditation" means accreditation by a NELAP approved accrediting body based on a laboratory's compliance to TNI Standards after a review of the laboratory's application, quality manual, PT results and on-site assessment results as described in the TNI Standards.¶
(23) "Proficiency testing (PT)" means the analysis of samples obtained from providers that meet the TNI standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.¶
(24) "Public water system" means a water system as defined in OAR 333-061-0010.¶

(25) "Quality Manual (QM)" means a document stating the management policies, objectives, principles, organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.¶
(26) "Resource Conservation and Recovery Act (RCRA)" means the enabling legislation, 42 U.S.C. section 6901 et seq. (1976), that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.¶
(27) "Safe Drinking Water Act (SDWA)" means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.¶
(28) "Scheduled proficiency testing" means a single complete sequence of circulation and scoring of proficiency testing sample for a participant in a proficiency test program with predefined opening and closing dates for any participant. ¶
(29) "Secondary accreditation" means the recognition by reciprocity for the fields of accreditation, methods and analytes for which the laboratory holds current primary accreditation by another NELAP approved accrediting body.¶
(30) "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act. Cannabinoid products and concentrates or extracts as defined in ORS 475B.550 shall be included in this matrix as solids.¶
(31) "Supplemental proficiency testing" means a PT study that may be from a lot previously released by a PT provider but that does not have a pre-determined opening date and closing date but the closing date cannot exceed 45 days from the opening date.¶
(32) "TNI" means the NELAC Institute. TNI is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.¶
(33) "TNI Standards" means the adopted TNI Standards (© 20~~09~~16 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¶
(34) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0120.¶
(35) "Third party assessor" means an ORELAP approved assessor who has a current contract with the Oregon Health Authority to perform on-site assessments of laboratories for ORELAP and is not employed by the state agencies comprising ORELAP's accrediting body.¶
(36) "United States Environmental Protection Agency (EPA)" means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (that is air, water, and land) upon which human life depends.¶
~~[Publications: Publications referenced are available from the agency.]~~
Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150~~(1)~~, 448.280~~(1)(b), (2),~~ 475B.555, 475B.565
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280~~(1)(b), (2),~~ 475B.555, 475B.565

AMEND: 333-064-0035

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0035 “Approval Requirements”: Addition of reasons for denial of an initial application and reasons for suspension or revocation in total or in part of a laboratory’s accreditation. The language is based on Volume 2 of the 2016 TNI Standard. This change is intended to inform laboratories what infractions typically trigger accreditation decisions to deny, suspend, or revoke accreditation.

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) 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) Laboratory's participation in proficiency testing (PT) and the obtaining of acceptable PT results according to the TNI Standards;¶
(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) Laboratory's full payment of all appropriate fees as described in OAR 333-064-0060.
Statutory/Other Authority: ORS 448.150~~(1)~~, 448.131, 448.280~~(1)(b)(2)~~, 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565
Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565

AMEND: 333-064-0045

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0045 “Procedure for Contesting Action of ORELAP”: Update to section organization for clarity. Addition of language clarifying the responsibility of the program to provide formal written notice of intended action to the laboratory. Addition of language clarifying that actions based on proficiency testing failure are not eligible for a contested case hearing. These changes are intended to inform the laboratories about their right to request a contested case hearing.

CHANGES TO RULE:

333-064-0045
Procedure for Contesting Actions of ORELAP ¶

(1) The procedure for contesting the actions of ORELAP regarding denial, suspension and revocation of accreditation, or other changes in accreditation status is in accordance with the Administrative Procedures Act, ORS ~~183~~chapter 183.¶
(2) Laboratories shall be provided formal written notice of intended action and their right to request a contested case hearing.¶
(3) Actions based on PT failures are not eligible for a contested case hearing.
Statutory/Other Authority: ORS 448.150~~(1) & 448.131, 448.280(1)(b) & (2)~~, 448.280, 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565, 448.131
Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475B.555, 475B.565

AMEND: 333-064-0060

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0060 “Fee Schedule”: Update to language specifying that third-party assessment fees will be paid directly to ORELAP upon the laboratory's consent to the third-party assessment instead of directly to the third-party assessors. This change is being made to align with ORS 438.620.

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 three levels of fees, Tier 1 at $450, Tier 2 at $900 and Tier 3 at $1,600 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 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 and 26 or more points are Tier 3 laboratories.¶
(b) For each out-of-state laboratory requesting primary or secondary accreditation through ORELAP, one of three levels of fees, Tier 1 at $1,650, Tier 2 at $2,640 and Tier 3 at $3,960 will be charged with each Tier determined according to subsection (1)(a) 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, when ORELAP personnel will be used for the assessment, will be charged an assessment fee as follows:¶
(a) Oregon laboratories will be charged $90 and out-of-state laboratories will be charged $120 for each of the following Basic Fields of Accreditation requested for accreditation:¶
(A) Gravimetric;¶
(B) Physical;¶
(C) Probe.¶
(b) Oregon laboratories will be charged $350 and out-of-state laboratories will be charged $462 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);¶
(I) Asbestos - electron microscopy.¶
(c) Oregon laboratories will be charged $500 and out-of-state laboratories will be charged $660 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) immunoassay;¶
(J) Radiochemistry.¶
(d) Oregon laboratories will be charged $1,000 and out-of-state laboratories will be charged $1,440 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 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) All Oregon laboratories requesting primary accreditation through ORELAP where Oregon state assessor(s) will perform the on-site assessment must pay an on-site trip fee for each on-site assessment. For a mobile category 2 laboratory, the trip fees 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.¶
(a) On-site trip fees are $350 for Tier 1, $500 for Tier 2 and $1,000 for Tier 3 laboratories with the Tiers determined according to subsection (1)(a) of this rule.¶
(b) All laboratories must pay the appropriate on-site trip fee for performing each required on-site assessment and additional assessments as requested by the laboratory for accreditation for additional fields of accreditation and matrices.¶
(c) All laboratories must pay the appropriate on-site trip fee per on-site assessment performed due to just cause according to TNI Standards.¶
(7) All laboratories located in Oregon requesting primary accreditation through ORELAP where ORELAP has determined ~~that~~ third party assessors will be used, must pay ~~ORELAP application assessment fees plus all~~all the third party assessor's costs~~.~~ to ORELAP ~~may require~~upon the laboratory~~ to pay the on-site assessment costs directly to the third party assessor according to the schedule of the assessor for all required on-site~~'s written consent to the third party assessments~~.~~¶
(8) 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 lab that have not been requested by its fixed based facility. If third party assessors are used, ~~ORELAP may require the lab to pay the on-site~~the out-of-state laboratory must pay all the third party assess~~ment~~or's costs ~~directly to the assessor according to the schedule of the assessor for all required inspections~~to ORELAP upon the laboratory's written consent to the third party assessment.¶
(9) 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;¶
(c) An on-site trip fee, as described in subsection (6)(a) and section (8) of this rule, based only on the additional parameters if ORELAP determines that an on-site assessment is required.
Statutory/Other Authority: ORS 438.605 - 438.620, 448.280~~(1)(b), (2)~~, 475B.555, 475B.565
Statutes/Other Implemented: ORS 438.605 - 438.620, 475B.555, 475B.565

AMEND: 333-064-0065

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0065 “Civil Penalties”: Housekeeping revision to language for clarity.

CHANGES TO RULE:

333-064-0065
Civil Penalties ¶

(1) In addition to any other penalty provided by law, the Oregon Health Authority, in collaboration with the accrediting body, may impose a civil penalty not to exceed $500 per day per violation upon any and all laboratories that:¶
(a) Falsely purport to be ORELAP accredited;¶
(b) Improperly use their ORELAP accreditation status in order to mislead; or¶
(c) Use the TNI\NELAP logo in catalogs, advertisements, business solicitations, proposals, quotations, laboratory reports and other materials without proper authorization.¶
(2) The Oregon Health Authority reserves the right to pursue other remedies and may take any other disciplinary action against alleged violators.¶
(3) In establishing the amount of the penalty for each violation, the Oregon Health Authority will consider, but not be limited to the following factors:¶
(a) The gravity and magnitude of the violation;¶
(b) The laboratory's previous record of complying or failing to comply with this rule.¶
(c) The laboratory's history in taking all feasible steps or in following all procedures necessary or appropriate to correct the violation; and,¶
(d) Such other considerations as the Oregon Health Authority may consider appropriate.¶
(4) The Oregon Health Authority in collaboration with the accrediting body may deny, suspend or revoke accreditation of any laboratory that fails to pay on demand a civil penalty that has become due and payable, provided that it first gives the laboratory an opportunity for a hearing as outlined in ORS chapter 183.
Statutory/Other Authority: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475B.585
Statutes/Other Implemented: ORS 448.280~~(1)(b) & (2)~~, 438.605, 438.610, 438.615, 438.620, 475B.585

AMEND: 333-064-0100

NOTICE FILED DATE: 10/28/2020

RULE SUMMARY: Amendments to OAR 333-064-0100 “Marijuana Item Sampling Procedures and Testing”: Update to the revision number of both the cannabis sampling protocols. ORELAP-SOP-001 updated to revision 4.0 and ORELAP-SOP-002 updated to revision 4.1. Changes are being made to update the reference to the 2009 TNI Standard to just “TNI Standard”. A major update to the formatting of both SOPs was made based on input from Department of Justice and former staff. These changes will improve organization and effectively communicate the requirements. Changes include: Updated the state public health laboratory address and titles of authorizing signatories on the SOPs; Updated definitions to match definitions in statutes and rules; Added Tables for better organization; Added requirements for verification of field balances; Mention assigning divisions to layers in deep containers; and Updated ORELAP-SOP-002 to include the definition of kief and to include consideration of unusual sample matrices.

CHANGES TO RULE:

333-064-0100
Marijuana Item 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 sampling policies and procedures, accredited by ORELAP, that:¶
(A) Ensure sampling will result in a sample that is representative of the batch being sampled.¶
(B) Require sampling and laboratory personnel to document and collect any information necessary for compliance with these rules, OAR chapter 333, division 7, and any applicable TNI standards. ¶
(C) Require chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8.¶
(D) Are appropriate to the matrix being sampled.¶
(E) Are consistent with OAR 333-007-0360 and 333-007-0370 and the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:¶
(i) Usable Marijuana: ORELAP-SOP-001 Rev ~~3.14~~4.0; and¶
(ii) Concentrates, Extracts, and Products: ORELAP-SOP-002 Rev ~~3.3. [Sampling protocols may be found on the ORELAP and Cannabis Testing webpage, public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx]~~ 4.1.¶
(F) Ensure that only the finished cannabinoid concentrate, extract or product is sampled if testing on the finished cannabinoid concentrate, extract or product is required under OAR 333-007-0330 and OAR 333-007-0340. ¶
(G) Contain training and education requirements for sampling personnel. ¶
(b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana samples being taken. ¶
(c) Laboratory personnel that perform sampling must:¶
(A) Comply with the laboratory's accredited sampling policies and procedures.¶
(B) After taking samples:¶
(i) Document the samples in accordance with subsection (2)(e) of this rule; and ¶
(ii) If sampling for a licensee or a registrant required to comply with CTS tracking under ORS 475B.895, record the sampling and transfer information in the Commission's seed to sale system, as required by the Authority and the Commission; and¶
(C) Take care while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.¶
(D) Take sample increments that are representative of the batch being sampled. ¶
(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by

the testing laboratory for these tests.¶
(e) A laboratory must comply with any recording requirements for samples and sample increments in the accredited policies and procedures and at a minimum:¶
(A) Record the location of each sample and sample increment taken.¶
(B) Assign a field identification number for each sample, sample increment and field duplicate that have an unequivocal link to the laboratory analysis identification.¶
(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.¶
(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.¶
(E) Place the laboratory identification code as a durable mark on each sample container.¶
(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.¶
(f) Combining sample increments.¶
(A) Sample increments collected from the same batch of usable marijuana must be combined into a single sample by a laboratory prior to testing. Sample increments from a batch of a cannabinoid concentrate, extract or product may be combined into a single sample by a laboratory prior to testing if the cannabinoid concentrate, extract or product has a certified control study.¶
(B) Sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360.¶
(C) Field duplicates may not be combined with the primary samples.¶
(3) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:¶
(a) Run a laboratory control standard in accordance with TNI standards requirements within acceptance criteria of 70 percent to 130 percent recovery.¶
(b) Analyze field duplicates of samples within precision control limits of plus or minus 20 percent RPD, if field duplicates are required.¶
(4) Calculating total THC and total CBD.¶
(a) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA:¶
M total delta-9 THC = M delta-9 THC + 0.877 x M delta-9 THCA.¶
(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA:¶
M total CBD = M CBD + 0.877 x M CBDA.¶
(c) Each test report must include the total THC and total CBD.¶
(5) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:¶
P total THC(dry) = P total THC(wet) / [1-(P moisture/100)]¶
P total CBD(dry) = P total CBD(wet) / [1-(P moisture/100)]¶
(6) Calculating RPD and RSD.¶
(a) A laboratory must use the following calculation for determining RPD:¶
Relative Percent Difference¶
%RPD=/(sample-duplicate)/(sample+duplicate)/2 x 100¶
(b) A laboratory must use the following calculation for determining RSD:¶
Standard Deviation¶
S= i=1n(xi-x)2(n-1)¶
Relative Standard Deviation¶

%RSD= Sx x 100¶
(c) For purposes of this section:¶
(A) S = standard deviation.¶
(B) n = total number of values.¶
(C) xi = each individual value used to calculate mean.¶
(D) x = mean of n values.¶
(d) For calculating both RPD and RSD if any results are less than the LOQ the absolute value of the LOQ is used in the equation.¶
(7) Tentative Identification of Compounds (TIC).¶
(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates or extracts for solvents and determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.¶
(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds).¶
(c) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration.¶
(d) Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to library spectrum.¶
(A) The top five matches over 90 percent must be reported by the lab¶
(B) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) =1.¶
(8) A laboratory must provide:¶
(a) Any pesticide test result to the Department of Agriculture upon that agency's request.¶
(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.¶
(9) A laboratory performing tests for a licensee or a registrant required to use CTS under ORS 475B.895 must enter any information required by the Commission or the Authority in CTS.¶
(10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.¶
(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-0400 to 333-007-0500 and these rules based on the state's needs.¶
(12) A laboratory must be able to demonstrate that its LOQ is below any action level established in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 and 4.¶
(13) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant or licensee may use methods not approved by the Authority but the laboratory may not identify those test results as accredited results.
Statutory/Other Authority: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555~~.~~, 475B.565
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555, 475B.565

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

Protocol for Collecting Samples of Usable Marijuana

ORELAP-SOP-001 Rev. 4.0

ORELAP Executive Board and Program Approval Signatures:

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John Fontana Ph.D., Oregon State Public Health Laboratory Director — Date: 11/25/2020

Kathleen Wickman, ODA Laboratory Manager — Date: 12/8/2020

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Sara Krepps, ORELAP QA Officer — Date: 12/07/2020

I. Table of Contents

Acknowledgements

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I. Introduction and Scope

Obtaining a representative sample from a larger batch 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.

This protocol is for use by ORELAP-accredited laboratories performing cannabis sampling as defined in OAR 333-064-0025. 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

ORELAP-accredited laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

1. The laboratory's SOP shall be readily accessible to all pertinent personnel.
2. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
3. 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.
4. All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-007-0310.

ORELAP-accredited laboratories shall maintain sampling plans.

1. The laboratory's sampling plans shall be made available at their location of use.
2. 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.
3. 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.
4. The laboratory's sampling plans shall document the date and time of sampling.

III. Client Contracts; 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 333-007-0315
2. A site-specific sampling plan or process specific sampling plan that uses statistical design for each project to provide representative sampling.

IV. Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the Usable Marijuana is being kept, as this will determine the sampling plan. In cases where Usable Marijuana will be sold or transferred to a processor or processing site, analysis may occur prior to the drying and curing steps. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for Usable Marijuana are in OAR 333-007-0320. The requirements for sampling and sample size are in OAR 333-007-0360 and Appendix 2. Per Authority or Commission request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan must be designed such that each flower bud in the batch has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 15 lbs**.

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. Standardized Sampling Plans can be included in the SOP however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.
2. Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity.
3. Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.
4. 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. Minimum weight or mass of each sample increment;
    d. Location of where sample increments will be taken within each container holding the

batch. See Appendix 2 for information on random selection of locations.

5. 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. Field balance (capable of 0.01 g measurements)
    f. Calibrated verification weights appropriate to verify accuracy of field balance
    g. Cleaning supplies – solvent, bleach, 70% Ethanol
    h. Gloves (powder-free, nitrile, sterile)
    i. Mylar bags (for final sample transport and storage) or amber glass jars (for final sample transport and storage)

2. Cleaning of Field Sampling Equipment
    a. Field sampling equipment shall be certified clean prior to use by the laboratory.
    b. Cleaning techniques 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 sampling equipment prior to taking that equipment into the field.
    e. Results from cleaning procedure tests 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 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. Procedures for Sampling Usable Marijuana

1. Locate the batch to be sampled. The sampler **must** have access to entire batch.
2. Check for any signs of non-uniformity within the batch and document the same.
    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 differences in the usable marijuana being sampled such as color, shape, size, and treatment.

   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 that 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 harvest lot number, producer, and other pertinent information. Each harvest lot must be separated into batches of 15 lbs. or less and must be assigned a unique batch number by the grower. Do not sample if a unique batch number is not available.
4. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container and confirm batch weight with client. Do not sample if the batch size is unavailable or exceeds 15 lbs.
5. Determine the number of containers from which sample increments must be collected (Appendix 2).
6. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
7. Sampling tool and other instruments like field balance must be clean prior to use to prevent cross-contamination of sample increments. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
   a. 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.
8. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
9. Decontamination waste must be collected and properly disposed of if not used for analysis.
   a. Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.
   b. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures or discarded.
   c. 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 Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6).
10. Visually inspect each test sample increment to assess uniformity. If non-uniformity is identified, record observation in the sampling report.
11. When collecting sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected. Laboratory should refrain from sampling a batch from containers that because of their shape make it impossible to collect sample increments from all locations within the container. This includes subsurface or internal layers.
12. Weigh each sample increment, document weight on sampling report form, along with location sample increment was taken.
13. Combine all sample increments to form the composite sample.
14. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
15. Seal and label the composite sample with the following minimum requirements:
   a. Laboratory license number

   b. Unique identifier for sampling event
   c. Sampling date and name of sampler
   d. Producer's license or registration number
   e. Harvest lot and batch numbers
   f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font.
16. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the laboratory sample identification number.
17. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the standards of accreditation.
18. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
19. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational marijuana or record in the laboratory's records the registrant number for tracking medical marijuana.

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler must complete a sampling report form for each batch sampled. Sample report forms must include at a minimum the following information:
   a. Name and address of producer including licensee or registrant number;
   b. Product type.
   c. Total weight of batch.
   d. Unique laboratory batch ID#, Metrc batch ID #, and/or OHA batch ID#.
   e. Total number of containers sampled.
   f. Number of sample increments taken from each container.
   g. Number of sample containers collected.
   h. Weight and location of each sample increment.
   i. Total weight sampled.
   j. Sampling plan ID and revision date.
   k. Sampling Procedure ID and revision date.
   l. Description of equipment and tools used.
   m. Address where sampled.
   n. Date sampled.
   o. ORELAP Laboratory Identification number.
   p. Lab License Number.
   q. Sampler's identification and/or signature.
   r. Name of responsible party for the batch and transport information.
   s. Receiving laboratory and types of tests required or requested.
2. A chain of custody form must be used unless the laboratory is sampling for a client that is required to use Metrc. A chain of custody form must include at least the following information:
   a. Sampler's name
   b. Sample Identification (Lab ID number) if assigned before arrival at laboratory
   c. Sampling Date/Time
   d. Weight and location of increment samples
   e. Final weight of composite sample
   f. Custody transfer signatures

g. Custody Transfer Dates/Times

3. If any of the above information requested on the sampling report form 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. Samples must be transported 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 harvest lot sampled and the chain of custody form continues to document sample integrity. Transportation must be done in compliance with OAR 845-025-5060. Note: The existing regulation 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 glass, amber jar with a PTFE-lined lid or a Mylar bag. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.
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 composite sample must be split for analysis by two different laboratories, for example when pesticide analysis is subcontracted to another laboratory, the composite sample shall be homogenized by the primary laboratory using the laboratory's approved sample homogenization process prior to subsampling. This shall be reflected on the chain of custody.
5. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

X. Quality Assurance and Quality Control

X.1 Sampler Qualifications

1. Basic qualifications for samplers of usable marijuana are:
    a. Physically able to perform the duties of a sampler;
    b. No conflict of interest;
    c. Employed by an ORELAP accredited laboratory
    d. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
    e. Licensed under state law to transport the required quantity of usable marijuana items
2. Education and training for samplers:
    a. Initial training: training shall include principles, procedures, and policies of sampling; Initial training must be performed by an Instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.
    b. Field or on-the-job training: 8-hours of training on various sampling techniques;

c. Continuing education: periodic refresher training shall be done annually.

X.2 Demonstration of Capability

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 IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method, and, 2) when the method has not been performed by the laboratory or sampler within a 12-month period.

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

1. Comparison of replicate samples within a defined Relative Standard Deviation (%RSD)[1].
2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD.

Thereafter, ongoing continuing demonstration of capability (CDOC) 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.

X.3 Field QC Samples

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

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

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

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

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

d. 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.

X.4 Field Audits

1. 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.
2. 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.
3. Required components of the Field Audit program:
    a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol;
    b. Observe the sampler conducting sampling procedures;
    c. Record any deficiencies and initiate corrective action.

XI. References

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

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

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

Appendix 1 Definitions

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

Authority means Oregon Health Authority

Batch means a quantity, not to exceed 15 pounds, of marijuana or usable marijuana from a harvest 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)

Commission means the Oregon Liquor Control Commission.

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

Container means a sealable, hard- or soft-bodied receptacle in which a marijuana item is placed during sampling, transport, and storage; or a physical division into which a marijuana batch is placed for random and representative sampling.

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

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

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

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

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

Heterogeneity means the state or quality of being heterogeneous.

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

Homogeneous means of a uniform composition and with similar properties throughout a batch of useable marijuana; means a cannabinoid product, concentrate, or extract has uniform composition and properties throughout each process lot.

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

Laboratory means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS475B.560.

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include

industrial hemp, as defined in ORS 571.300.

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

Metrc means the state-administered cannabis tracking system (CTS).

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.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.810.

Registrant means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS475B.810, 475B.840, or ORS 475B.858.

Relative Percent Difference means comparing two quantities while taking into account the size of what is being compared. If the final result (i.e. Total THC) 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. Total THC) 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 a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

Sample Increment means an amount of a marijuana item collected by laboratory personnel from a

registrant or licensee that may be combined into a sample for purposes of testing, or in the case of a control study, is tested individually.

Sample Quality Criteria (SQC) means a series of statements that clarify 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 prove authenticity or integrity of the sample.

Sterilization means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

TNI Standard: TNI Environmental Laboratory Standard as defined in 333-007-0310.

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

Appendix 2 Sampling Requirements

Random Sampling

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

1. Assign location numbers within containers and among a set of containers;
2. Use a random number generator to determine which locations to sample; and
3. Document where each sample increment was sampled from and the volume collected from each increment.

Assign divisions based on the type of container in the site-specific sampling plan. For container types that are greater than four (4) inches deep, divisions must also include a layer or layers beneath the accessible portion of the batch. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers use existing or arbitrary order of containers to assign numbers to the total of "divisions multiplied by total number of containers" (divisions x # containers = total number of random increments) and record in the sampling report.

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

Sample size

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

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

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

Batch size	Required sample size		
	Pounds (lbs)	Ounces (oz)	Grams (g)
≤1 lbs	0.005	0.08	2.3
1.01 ≤2 lbs	0.010	0.16	4.5
2.01 ≤3 lbs	0.015	0.24	6.8
3.01 ≤4 lbs	0.020	0.32	9.1
4.01 ≤5 lbs	0.025	0.40	11.3
5.01 ≤6 lbs	0.030	0.48	13.6
6.01 ≤7 lbs	0.035	0.56	15.9
7.01 ≤8 lbs	0.040	0.64	18.1
8.01 ≤9 lbs	0.045	0.72	20.4
9.01 ≤10 lbs	0.050	0.80	22.7
10.01 ≤11 lbs	0.055	0.88	25.0

Batch size	Required sample size		
	Pounds (lbs)	Ounces (oz)	Grams (g)
11.01 ≤12 lbs	0.060	0.96	27.3
12.01 ≤13 lbs	0.065	1.04	29.6
13.01 ≤14 lbs	0.070	1.12	31.9
14.01 ≤15 lbs	0.075	1.20	34.2

Sampling a batch

1. When collecting a primary sample from a batch, a minimum of seven (7) sample increments shall be collected. Collect the sample increments by following different paths through the batch container or by taking the sample increments systematically at well-separated points along a heptagonal pattern.
2. As the batch increases in size, it is necessary to collect additional sample increments to make up the primary sample (Table 2).

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

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

Size of batch (lbs)	≤ 12	≤ 14	≤ 15
No. of increments	9	10	10

Table 3 – Revision history of this SOP.

Revision	Date	Summary of changes made, and initials of editor
4.0	7/20/2020	Major updates and re-formatting, with input from Scott Hoatson and Department of Justice. Updated: OSPHL address; executive board and ORELAP staff names as needed; definitions in order to match OARs and ORS and arranged in alphabetical order. Added: this table (Revision history); subsection VI.3; additional information about subsampling for subcontracted analyses; mention of assigning layers for sampling deep containers; required calibration verification of field balances. Combined: information in section IX with information from former section X (Forwarding samples to the Primary and/or Retesting Laboratory) and deleted former section X and combined former section X.5 with section X.4. Minor updates for consistency and typo fixes. Includes fixing reference to minimum number of sample increments in Table 2. STJ 7/20/2020

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Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts and Products

ORELAP-SOP-002 Rev 4.1

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Acknowledgements

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I. Introduction and Scope

Obtaining a representative sample from a larger batch 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 manufacturing error is the responsibility of the processor of the cannabinoid concentrate, extract or 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.

This protocol is for use by ORELAP-accredited laboratories performing cannabinoid concentrate, extract, or product sampling as defined in OAR 333-064-0025. 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

ORELAP-accredited laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

1. The laboratory's SOP shall be readily accessible to all pertinent personnel.
2. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
3. 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.
4. All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-007-0310.

ORELAP-accredited laboratories shall maintain sampling plans.

1. The laboratory's sampling plans shall be made available at their location of use.
2. 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.

3. 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.
4. The laboratory's sampling plans shall document the date and time of sampling.

III. Client Contracts; 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 333-007-0315
2. A site-specific sampling plan or process specific sampling plan that uses statistical design for each project to provide representative sampling.
3. A request for a control study providing the information described in OAR 333-007-0440, if necessary.

IV. Planning

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

The testing requirements for cannabinoid concentrates and extracts are in OAR 333-007-0330; those for cannabinoid products are in OAR 333-007-0340. The requirements for sampling and sample size are in OAR 333-007-0360 and Appendix 2 of this protocol. Per Authority or Commission request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan must be designed such that any part or individual unit of sale in the batch or process lot has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required, including laboratory QC samples**.

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 or process lot. Standardized Sampling Plans can be included in the SOP however specialized

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

2. Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity.
3. Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.
4. A sampling plan must include at a minimum:
    a. Shape, size, and number of container(s) holding the batch or process lot 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. See Appendix 2 for information on random selection of locations.
5. 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. Field balance (capable of 0.01 g measurements)
    f. Calibrated verification weights appropriate to verify accuracy of field balance
    g. Cleaning supplies – solvent, bleach, 70% Ethanol
    h. Gloves (powder-free, nitrile, sterile)
    i. Mylar bags (for final sample transport and storage) or amber glass jars (for final sample transport and storage)

2. Cleaning of Field Sampling Equipment
    a. Field sampling equipment shall be certified clean prior to use by the

laboratory.
b. Cleaning techniques 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 sampling equipment prior to taking that equipment into the field.
e. Results from cleaning procedure tests 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 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. Procedures for Sampling Concentrates, Extracts, and Products.

1. Locate the cannabinoid concentrate, extract or product batch to be sampled. The sampler **must** have access to the entire batch or process lot.
2. Check for any signs of non-uniformity within the batch or process lot 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 differences in the marijuana items being sampled such as color, visible layers, size or 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 or process lot and that 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 and process lot number and other pertinent information. Do not sample if a unique batch and process lot numbers are not available.
4. Determine if the sample matrix is a liquid, semi- solid, or solid either in bulk form or in packaged units. Determine and record the total batch weight or volume and the number of containers comprising the batch. If the product is already in final packaging, determine and record the total number of final package units. Do not sample if there are deviations from the manifest or questions about the statistical certainty of the sampling plan.

5. Establish which tests will be performed. Ensure sufficient sample increments are taken to meet sample size requirements determined in the sampling plan and record the number of increments collected. The minimum sample amount is determined by the analytical method(s) being performed but can be no less than number of increments in OAR 333-007-0360, Exhibit B, Tables 5 and 6 (see Appendix 2) unless the product has successfully completed a control study. If the cannabinoid concentrate, extract or product has successfully completed a control study sample increments can be combined into one primary sample and one field duplicate sample. The sample increments for the primary sample and the field duplicate sample for cannabinoid concentrates and extracts are in OAR 333-007-0360, Exhibit B, Table 7. See additional details below if sampling for a certified control study.
6. Ensure that appropriate equipment and containers are used for the tests being performed. For residual solvent analysis, use glass amber containers that can be properly sealed to prevent the loss of solvent gas and minimize the headspace remaining in the sample container.
7. Select the appropriate sampling tool to ensure that it reaches all portions of the batch.
8. Collection instruments must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
    a. 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.
9. Results from cleaning procedures must be below the reporting limit of the target analyte(s) for the associated analyses.
10. Decontamination waste must be collected and properly disposed of if not used for analysis.
    a. Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.
    b. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.
    c. 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).
11. When collecting sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the

sampler to not damage the portion of the product which is not being collected. See sections below for more detail on sampling liquid, semi-solid, or solid sample matrices.

12. Once taken, seal and label the sample increments, composite sample, primary sample or field duplicate sample, as applicable with the following minimum requirements:
    a. Laboratory license number
    b. Unique identifier for sampling event
    c. Sampling date and name of sampler
    d. Processor's license or registration number
    e. Process lot and batch numbers
    f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font
13. Apply a custody seal to the sample container in a manner that prevents the marijuana item from being tampered with prior to testing. This seal may contain the laboratory sample identification number.
14. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the standards of accreditation.
15. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
16. Record the sampling event in the OLCC seed to sale system under the licensee number or under the registrant number, as applicable.
17. Apply the following guidelines when taking **Solid** and **Semi-Solid** samples:
    a. Establish the total batch weight or volume. If the batch is in final product packaging, determine how many units of sale there are and the total batch mass.
    b. Each sample increment should be taken from a randomly chosen position in the batch, as far as practically possible. A sample increment should 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. If permitted by OHA's rules, sample increments may be combined into a composite sample, or a primary sample and field duplicate sample, as applicable, depending on whether the concentrate, extract or product has a certified control study.
    c. The sample increments should consist of sufficient material to perform the required laboratory methods, between 1 gram +/- 0.2g. However, if this does not supply sufficient mass for required analysis, the mass of the sample increments can be increased or decreased as long as they are equivalent to each other.
    d. The minimum number of sample increments is in OAR 333-007-0360,

Exhibit B and included in Appendix 2, but more sample increments may be collected at client request based on the statistical design in the site-specific sampling plan. If not using the minimum requirements in rule the laboratory shall use its statistical design training, procedures, and calculators to determine the increments needed for a confidence interval that meets the client request.

e. Consideration must be taken for specific concentrate, extract, or product types that may be difficult to sample or weigh due to the physical nature of the item. When a sample type, such as kief, requires deviation from laboratory protocols, it is the responsibility of the sampler to document the actions taken.

f. Store each sample increment or combine all sample increments if allowed, as specified in the site-specific sampling plan, in an amber glass container to form the sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the sample increments are combined into a primary sample, complete the same procedure with a second set of equivalent sample increments to form the field duplicate sample.

18. 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 processor would use to disperse the concentrate, extract or product into packaging. Use an appropriate sample device for sampling bulk liquid in a container. Collect the appropriate number of sample increments based on the site-specific sampling plan for the client.

    b. Store each sample increment or combine all sample increments if allowed, as specified in the site-specific sampling plan, in an amber glass PTFE screw top container to form the sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the sample increments are combined into a primary sample, complete the same procedure with a second set of equivalent sample increments to form the field duplicate sample.

Sampling process when a Control Study is requested

1. Ensure that processor or processing site has completed the control study requirements as specified under OAR 333-007-0440(1).
2. Locate the batch of cannabinoid concentrate, extract, or product to be sampled for the control study.
3. Review the batch label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot number is not available or does not match the written request for the control study.

4. Visually inspect the batch to assess uniformity across containers or units for sale.
5. Determine the size of batch by reviewing the written request for the control study.
6. Determine the number of sample increments necessary based on total size of the batch. The minimum increments necessary are in OAR 333-007-0360, Exhibit B, Tables 5 and 6 and included in Appendix 2. For cannabinoid products each sample increment consists of an entire unit of sale. Additional increments may be required to ensure that sufficient quantity of material is available for all required tests.
7. Additional information and requirements for sampling concentrates, extracts and products are in the sections above.
8. Sample increments taken for a control study **may not be combined** into a composite sample. The increments being collected must be obtained as described above in this protocol.

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

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler must complete a sampling report form for each batch or process lot sampled. Sample report forms must include at a minimum the following information:
    a. Name and address of producer including licensee or registrant number;
    b. Product type.
    c. Total weight of batch or total number of units of sale of batch.
    d. Unique laboratory batch ID#, Metrc batch ID #, and/or OHA batch ID#.
    e. Applicable Control Study Certificate, agency documentation, and expiration dates of these.
    f. Total number of containers sampled.
    g. Number of sample increments taken from each container.
    h. Number of sample increments combined into a field primary and field duplicate sample, if applicable
    i. Number of sample containers collected.
    j. Weight and location of each sample increment.
    k. Total weight sampled.

   l. Sampling plan ID and revision date.
   m. Sampling Procedure ID and revision date.
   n. Description of equipment and tools used.
   o. Address where sampled.
   p. Date sampled.
   q. ORELAP Laboratory Identification number.
   r. Lab License Number.
   s. Sampler's identification and/or signature.
   t. Name of responsible party for the batch and transport information.
   u. Receiving laboratory and types of tests required or requested.
2. A chain of custody form must be used unless the laboratory is sampling for a client that is required to use Metrc. A chain of custody form must include at least the following information:
   a. Sampler's name
   b. Sample Identification (Lab ID number) if assigned before arrival at laboratory
   c. Sampling Date/Time
   d. Weight and location of increment samples
   e. Final weight of composite sample
   f. Custody transfer signatures
   g. Custody Transfer Dates/Times
3. If any of the above information requested on the sampling report form 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 sample increments or 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 process lot sampled and the chain of custody form continues to document sample integrity. Transportation must be done in compliance with OAR 845-025-5060. 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 an amber glass jar with a PTFE-lined lid or a Mylar bag and should be appropriate for the sample matrix and the tests required. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.
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 sample increments or composite sample to the laboratory in its entirety. In a situation where the composite sample must be split for analysis by two different laboratories, for example when residual 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 and to prevent the loss of volatile components. This shall be reflected on the chain of custody.
5. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

X. Quality Assurance and Quality Control

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

Sampler qualifications

1. Basic qualifications for samplers of marijuana items are:
    a. Physically able to perform the duties of a sampler;
    b. No conflict of interest;
    c. Employed by an ORELAP accredited laboratory;
    d. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
    e. Licensed under state law to transport the required quantity of marijuana items.
2. Required education and training for samplers:
    a. Initial training: training shall include principles, procedures, and policies of sampling; Initial Training must be performed by an Instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.
    b. Field or on-the-job training: 8-hours of training on various sampling techniques.
    c. Continuing education: periodic refresher training shall be done annually.

Demonstration of Capability

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 IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method; and 2) when the method has not been performed by the laboratory within a 12-month period.

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

1. Comparison of replicate samples within defined Relative Standard Deviation (%RSD) acceptance criteria.
2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within defined Relative Percent Difference (%RPD) acceptance criteria.

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.

Field QC Samples

1. Field Duplicates
    a. A Field Duplicate Sample is required for any sampling event that takes place after a control study has been certified according to OAR 333-007-0440. The Field Duplicate must be collected using the same procedure as the Field Primary. Comparison of Field Primary and Field Duplicate results must be evaluated against %RPD or %RSD requirements as specified in the applicable OAR sections.

2. Equipment Blanks

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

    b. The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the

detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.

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

d. 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.

3. Transport Blank

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

Field Audits

1. 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.
2. 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.
3. Required components of the Field Audit program:
   a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol.
   b. Observe the sampler conducting sampling procedures.
   c. Record any deficiencies and initiate corrective action.

XI. References

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Appendix 1 – Definitions

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

Authority means Oregon Health Authority

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

CBD means Cannabidiol, Chemical Abstracts Service number 13956-29-1.

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)

Commission means the Oregon Liquor Control Commission.

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

Container means a sealable, hard- or soft-bodied receptacle in which a marijuana item is placed during sampling, transport, and storage; or a physical division of an extract or concentrate process lot for random sampling.

Control Study means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through sampling and testing as described in OAR 333-007-0440.

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

Delta-9 THC is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service number 1972-08-3.**Equipment Blank** means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate cleaning procedure or between sampling batches to demonstrate lack of contamination.

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

Fundamental Sampling Error (FSE) means 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 cannabinoid product, concentrate, or extract has uniform composition and properties throughout each process lot.

Kief means the resinous trichomes of marijuana that accumulate or fall off when marijuana flowers are sifted through a mesh screen or sieve.

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

Laboratory means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under ORS475B.420.

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

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

Metrc means the state-administered cannabis tracking system (CTS).

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 means

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

(b) Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract as defined in subsection (a) above.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.810.

Registrant means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.810, 475B.840, or 475B.858.

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. Total THC) 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. Total THC) 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 marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

Sample Increment means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing or, in the case of a control study, is tested individually.

Sample Quality Criteria (SQC) means a series of statements that clarify 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.

Sterilization means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

THC means tetrahydrocannabinol and has the same Chemical Abstracts Service number as delta-9 THC.

THCA means tetrahydrocannabinolic acid, Chemical Abstracts Service number 23978-85-0.

TNI Standard means the TNI Environmental Laboratory Standard as defined in OAR 333-007-0310

Total THC means the molar sum of THC and THCA.

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

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

product of producing or processing marijuana.

Appendix 2 – Sampling Requirements

Random sampling

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

1. Assign location numbers within containers and among a set of containers;
2. Use a random number generator to determine which location to sample; and
3. Document where each sample increment was sampled and the volume or mass collected from each increment.

Assign divisions based on the type of container in the site-specific sampling plan. For container types that are greater than four (4) inches deep, divisions must also include a layer or layers beneath the upper portion of the container. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers, use existing or arbitrary order of containers to assign numbers to the total of "divisions multiplied by total number of containers" (divisions x # containers = total number of random sample increments) and record in the sampling report.

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

Sample size and increments

Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required.

The required sample increments for a given batch or process lot of cannabinoid concentrate or extract varies depending upon the size of the batch. (See Table 1)

Table 1 – Sample increment requirements based on size of concentrate or extract batch. (From 333-007-0320, Exhibit B, Table 5)

Batch Weight		Sample Increments Required
Pounds	Kilograms	
0-0.50	0-0.23	4
0.51-1.5	0.24-0.68	8
1.51-3.00	0.69-1.36	12
3.10-6.00	1.40-2.72	16
6.10-10.00	2.77-4.54	20
10+	4.58+	32

The required sample increments for a given batch or process lot of cannabinoid products as specified in OAR 333-007-0360 varies depending upon the number of units of sale in the batch. (See Table 2)

Table 2 – Sample increment requirements per batch size of cannabinoid products. (From 333-007-0320, Exhibit B, Table 6)

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

The required number of sample increments for a given batch or process lot of cannabinoid concentrate or extract with a certified control study in place varies depending upon the size of the batch. Sample increments are combined into a primary sample. An equivalent number of increments sampled using the same procedure are combined into the field duplicate sample. The primary and field duplicate samples are put in separate containers and are prepared and analyzed separately. (See Table 3)

Table 3 – Sample increment requirements based on size of concentrate or extract batch with a certified control study. (From 333-007-0320, Exhibit B, Table 7)

Batch Weight		Sample Increments Required	
Pounds	Kilograms	Primary	Field Duplicate
0-0.50	0-0.23	2	2
0.51-1.5	0.24-0.68	4	4
1.51-3.00	0.69-1.36	6	6
3.10-6.00	1.40-2.72	8	8
6.10-10.00	2.77-4.54	10	10
10+	4.58+	16	16

Table 4 – Revision history of this SOP.

Revision	Date	Summary of changes made, and initials of editor
4.0	07/22/2020	Major updates and re-formatting based on input from Scott Hoatson (former ORELAP QA Officer) and Department of Justice. Updated: OSPHL address; executive board and ORELAP staff names/titles as needed; definitions in order to match OARs and ORS. Added: Tables 1, 2, 3, and 4 (this table); information regarding required calibration verification of field balances; mention of assigning divisions to layers in deep containers; section II; section III; condensed general document requirements in new section II, and specific sampling forms under section VIII; condensed Planning section, now section IV; reference to FDA aseptic sampling document; definition of Metrc. Combined: sampling design and plans and representative sampling sections; forwarding samples section with transportation section Minor updates and typo fixes for consistency with Useable Marijuana sampling SOP.

		STJ 07/22/2020
4.1	10/19/2020	Minor updates to include definition of kief and inclusion of consideration of tricky/unusual sample matrices in section 17 e. STJ 10/19/2020