DRAFT

08/~~2~~30/2021

Division 64
ACCREDITATION OF LABORATORIES

333-064-0010
Scope

(1) These rules apply to:

(a) Laboratories seeking accreditation to perform environmental or agricultural laboratory testing;

(b) Laboratories seeking accreditation to perform sampling and laboratory testing of marijuana items and industrial hemp-derived vapor items as required by ORS 475B.565; and

(c) Accredited laboratories performing:

(A) Environmental or agricultural testing; or

(B) Sampling and testing of marijuana items and industrial hemp-derived vapor items.

(2) Accreditation as described in these rules is required for all laboratories reporting drinking water analysis results to the Oregon Health Authority except for Oregon Department of Agriculture Laboratory, Oregon Department of Environmental Quality Laboratory and the Oregon State Public Health Laboratory which must be certified by the United States Environmental Protection Agency for drinking water analysis.

(3) Accreditation as described in these rules is required for all Oregon laboratories testing marijuana items and industrial hemp-derived vapor items.

Statutory/Other Authority: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620, 475B.565 & 475B.555
Statutes/Other Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615, 438.620, 475B.565 & 475B.555
History:
PH 31-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 17-2016, f. & cert. ef. 6-7-16
PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16
PH 6-2011, f. & cert. ef. 8-9-11
PH 20-2003, f. 12-02-03, cert. ef. 12-08-03
PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04
OHD 16-2002, f. & cert. ef. 10-10-02
OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0025
Definitions

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

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

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

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

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

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

(6) "Batch" means:

(a) For sample analysis, this term has the meaning assigned in the TNI Standard which is: a group of samples that are prepared and/or analyzed together in the laboratory with the same process and personnel, using the same lot(s) of reagents. A preparation batch is composed of one (1) to twenty (20) environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing the first and last sample in the batch to be twenty-four (24) hours. An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed twenty (20) samples.

(b) For cannabis sampling, this term means:

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

(B) A quantity of cannabinoid concentrate, extract, product, or industrial hemp-derived vapor item from a process lot.

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

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

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

(106) "Cannabis Tracking System" or "CTS" has the meaning given that term in OAR 333-007-0310.~~means the Oregon Liquor Control Commission's system for tracking the transfer of marijuana items and other information as authorized by ORS 475B.177.~~

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

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

(137) "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.

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

(15) "Commission" means the Oregon Liquor and Cannabis Commission.

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

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

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

(199) "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.

(2010) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.

(2111) "Finished cannabinoid concentrate or extract" has the meaning given that term in OAR 333-007-0310. ~~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.~~

(2212) "Finished cannabinoid product" has the meaning given that term in OAR 333-007-0310.~~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.~~

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

(2413) "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.

(2514) "Marijuana item" has the meaning given that term in OAR 333-007-0310~~ORS 475B.550~~.

(2615) "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.

(27~~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.

(28~~17~~) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.

(29~~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.

(30~~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.

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

(32~~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.

(33~~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.

(34~~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.

(35~~24~~) "Public water system" means a water system as defined in OAR 333-061-0010.

(36~~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.

(37~~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.

(38~~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.

(39~~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.

(40~~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.

(41~~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 and industrial hemp-derived vapor items as defined in OAR 333-007-0310~~ORS 475B.550~~ shall be included in this matrix as solids.

(42~~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.

(43~~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.

(44~~33~~) "TNI Standards" means the adopted TNI Standards (© 2016 The NELAC Institute), which are documents describing the elements of laboratory accreditation that was developed and established by the consensus principles of TNI and meets the approval requirements of TNI procedures and policies. Available at www.nelac-institute.org

(45~~34~~) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0120.

(46~~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.

(47~~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.

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150, 448.280, 475B.555 & 475B.565
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280, 475B.555 & 475B.565

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PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 17-2016, f. & cert. ef. 6-7-16
PH 31-2015(Temp), f. 12-29-15, cert. ef. 1-1-16 thru 6-28-16
PH 6-2011, f. & cert. ef. 8-9-11
PH 8-2005, f. 6-1-05, cert. ef. 7-1-05
PH 23-2004, f. & cert. ef. 7-1-04
PH 20-2003, f. 12-02-03, cert. ef. 12-08-03
PH 13-2003(Temp), f. & cert. ef. 9-22-03 thru 3-20-04
PH 5-2003, f. 5-15-03, cert. ef. 7-1-03
OHD 16-2002, f. & cert. ef. 10-10-02
OHD 1-2001, f. & cert. ef. 1-17-01
OHD 7-1999, f. & cert. ef. 10-26-99

333-064-0100
~~Marijuana Item~~ Cannabis Sampling Procedures and Testing

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

(2) Sampling.

(a) A laboratory must have and follow marijuana item and industrial hemp-derived vapor items sampling policies and procedures, accredited by 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 ~~4.0~~X.X; and

(ii) Concentrates, Extracts, ~~and~~ Products and Industrial Hemp-derived Vapor Items: ORELAP-SOP-002 Rev ~~4.1~~X.X.

Commented [JS1]: Placeholders for updated revision numbers of sampling protocols.

(F) Ensure that only the finished cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item is sampled if testing on the finished cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item 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 or industrial hemp-derived vapor item samples being taken.

(c) Laboratory personnel that perform sampling must:

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

(B) After taking samples:

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

(ii) If sampling for a licensee or a registrant required to comply with 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 or industrial hemp-derived vapor item may be combined into a single sample by a laboratory prior to testing if the cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item has a certified control study. ~~Prior to any testing, the combined sample must undergo the laboratory's homogenization process. If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis.~~

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

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

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

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

(a) Run a laboratory control standard for all adult use cannabinoids required per OAR 333-007-0430, CBD, and CBDA in accordance with TNI ~~s~~Standard~~s~~ requirements within acceptance criteria of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples with~~in~~ a precision ~~control~~ limit~~s~~ of ~~plus or minus~~ 20 percent RPD, if field duplicates are required. The amount of delta-8 THC, total delta-9 THC, or total CBD between the primary sample and field duplicate may not exceed 15 percent RPD for concentrates, extracts, products, or industrial hemp-derived vapor items that have a control study in place.

Commented [JS2]: Copied from 333-007-0430 (3) (a).

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

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

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

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

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

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

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

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

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

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

(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) * 100

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

Standard Deviation

S= √(∑((xi–x)^2)/(n–1))

Relative Standard Deviation

%RSD= (S/x)* 100

(c) For purposes of this section:

(A) S = standard deviation.

(B) n = total number of values.

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

(D) x = mean of n values.

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

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

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

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates, ~~or~~ extracts, or industrial hemp-derived vapor items 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~~shall have an established procedure for achieving tentative identification of unknown compounds in the sample. A tentatively identified compound (TIC) means an unknown chromatographic peak that is neither included in the list of analytes

the laboratory is testing for nor expected to be naturally found in cannabis concentrates, extracts, or industrial hemp-derived vapor items such as terpenes.

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

(c) Upon written request from the overseeing agency of the licensee or registrant, ~~A~~a laboratory shall report to the licensee or registrant and the Authority or the Commission~~, depending on which agency has jurisdiction, up to five~~ all tentatively identified compounds (TICS) that ~~have the greatest apparent concentration~~meet the identification criteria in (b) of this rule.

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

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

~~(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:

(a) Below any action level established in OAR 333-007-0400 and 333-007-0410, Exhibit A, Tables 3 and 4; and

(b) For total delta-9 THC concentration below 0.3 percent.

Commented [JS3]: Require an LOQ of less than 0.3 percent for delta-8 THC?

(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.

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

Statutory/Other Authority: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555 & 475B.565
Statutes/Other Implemented: ORS 438.605, 438.610, 438.615 & 438.620, 475B.555 & 475B.565
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PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-064-0110
Reporting ~~Marijuana~~ Cannabis Test Results

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Statutory/Other Authority: ORS 475B.555 & ORS 475B.565
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PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
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333-064-0120
Proficiency Testing for Laboratories Accredited for Cannabis Testing

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

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

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

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

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

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

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

(A) The laboratory's name and address;

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

(C) The method and analyte codes.

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

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

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

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

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

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

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

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

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

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

Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555
History:
PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 65-2020, temporary amend filed 09/24/2020, effective 09/24/2020 through 03/22/2021
PH 45-2020, minor correction filed 05/07/2020, effective 05/07/2020
PH 282-2018, adopt filed 12/20/2018, effective 01/01/2019