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Division 64
ACCREDITATION OF LABORATORIES

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 ~~4.03-1~~; and

(ii) Concentrates, Extracts, and Products: ORELAP-SOP-002 Rev ~~4.03-3~~. [Sampling protocols may be found on the ORELAP and Cannabis Testing webpage,

public.health.oregon.gov/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/cannabis-info.aspx].

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

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

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

(c) Laboratory personnel that perform sampling must:

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

(B) After taking samples:

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

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

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

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

(d) A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.

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

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

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

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(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. 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) 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:

$M \text{ total delta-9 THC} = M \text{ delta-9 THC} + 0.877 \times M \text{ delta-9 THCA}$.

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

$M \text{ total CBD} = M \text{ CBD} + 0.877 \times M \text{ CBDA}$.

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

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

$P \text{ total THC(dry)} = P \text{ total THC(wet)} / [1 - (P \text{ moisture}/100)]$

$P \text{ total CBD(dry)} = P \text{ total CBD(wet)} / [1 - (P \text{ moisture}/100)]$

(6) Calculating RPD and RSD.

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

Relative Percent Difference

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

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

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Standard Deviation

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

Relative Standard Deviation

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

(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.

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

(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:

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

(b) For THC concentration below 0.3 percent.

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(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.

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615 & 438.620 & 475B.555

333-064-0110

Reporting Marijuana 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.

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

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

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

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

(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 changed if necessary to reflect the amended report. The laboratory shall ensure that the amended report, communication, and changes 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.

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

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

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

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

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

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555