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## NOTICE OF PROPOSED RULEMAKING

INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333

**OREGON HEALTH AUTHORITY**

**PUBLIC HEALTH DIVISION**

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**FILED: 09/30/2026 12:47 PM**

ARCHIVES DIVISION SECRETARY OF STATE

FILING CAPTION: Marijuana, hemp, and psilocybin testing

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 10/21/2026 5:00 PM

*The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.*

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Filed By:

Public Health Division

Rules Coordinator

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### HEARING(S)

*Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.*

DATE: 10/19/2026

TIME: 1:00 PM

OFFICER: Staff

### REMOTE HEARING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 971-277-2343

CONFERENCE ID: 780089180

### SPECIAL INSTRUCTIONS:

This hearing is being held remotely via Microsoft Teams. To provide oral (spoken) testimony during this hearing, please contact [publichealth.rules@odhsoha.oregon.gov](mailto:publichealth.rules@odhsoha.oregon.gov) to register to receive the link for the Microsoft Teams video conference via calendar appointment, or you may access the hearing using the meeting URL above. Alternatively, you may dial 971-277-2343, Phone Conference ID 780 089 180# for audio (listen) only. This hearing will close no later than 2:00PM but may close as early as 1:30 PM if everyone who signs up to provide testimony has been heard from.

Accessibility Statement: For individuals with disabilities or individuals who speak a language other than English, OHA can provide free help. Some examples are: sign language and spoken language interpreters, real-time captioning, braille, large print, audio, and written materials in other languages. If you need help with these services, please contact the Public Health Division at 971-673-1222, 711 TTY or [publichealth.rules@odhsoha.oregon.gov](mailto:publichealth.rules@odhsoha.oregon.gov) at least 48 hours before the meeting. All relay calls are accepted. To best ensure our ability to provide a modification please contact us if you are considering attending the meeting and require a modification. The earlier you make a request the more likely we can meet the need.

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#### NEED FOR THE RULE(S):

Oregon Health Authority (OHA) is proposing amendments to rules in OAR chapter 333, division 7 and 64 pertaining to marijuana and hemp testing to address technical issues such as correcting errors, improving clarity, accuracy and consistency amongst laboratory testing, and removing outdated provisions tied to past dates related to cannabis testing. These amendments are technical and primarily clarifying in nature. They help to remove ambiguities and promote consistency, ensuring enforcement remains aligned with existing regulatory frameworks. In addition, changes to psilocybin testing will also be made in division 64. Changes related to psilocybin testing found in division 64 are also technical and primarily clarifying in nature for testing laboratories.

The following is a summary of division 7 proposed changes.

One proposed change would allow registrants and licensees the option to provide a target potency to a testing laboratory prior to sampling when ordering a potency test on a cannabinoid product. Processors that create products follow standard operating procedures designed to achieve a specific potency, ensuring that they create a consistent product every time it is made. They also often purchase large quantities of printed labels with that target amount to be displayed on the principal display panel. Under Oregon Liquor and Cannabis Commission (OLCC) rules, actual potency may vary by plus or minus 10.0% from the labeled target for products. In some cases, a test result may fall outside the intended target potency but still remain within allowable OLCC concentration limits, meaning the product does not fail testing. Current rules do not permit re-testing in these situations. The proposed amendment would allow a re-analysis or re-test if the result deviates from the target potency by more than 10.0%, following an investigation by the registrant or licensee to confirm that protocols were followed during manufacturing and the correct input materials were used. This change supports more accurate labeling, helps prevent unnecessary product waste, and ensures products are manufactured as intended. This amendment applies to cannabinoid products because target potencies are almost exclusively utilized for cannabinoid products and they are typically the most straightforward category to formulate to a target. How the product is to be re-analyzed and re-tested is outlined in the rule changes. The last potency test result obtained will be considered the final result.

Another change clarifies that when ordering potency tests on cannabinoid products, the registrant or licensee must provide the weight or mass of all serving sizes and units of sale. This ensures laboratories can calculate potency accurately for multi-unit products and verify they meet the OLCC's concentration limits. This clarification supports accurate testing while maintaining existing testing practices and does not introduce new requirements.

Clarification is added to the rule language to state a sufficient sample size must be obtained for analysis of all requested tests, including any potential re-analysis test that may also be requested. This language change maintains existing sampling practices and does not introduce new requirements, it only clarifies them.

The action levels listed in Exhibit A will be updated to include a trailing zero (for example, changing 1.2 to 1.20 or 1 to 1.0). In addition, throughout the rules a trailing zero is being added to units of measure such as weights, percents, relative

percent difference (RPD), relative standard deviation (RSD), and measure of cannabinoids. This added zero is a significant figure, which means laboratories must round their measured results to that decimal place. The numerical action limits or numbers are not changing; only the formatting of the values is being updated. This change clarifies when a result is considered a failure and ensures laboratories apply rounding consistently. Rule language for each test type will be revised to state explicitly that a result fails if it is at or above the action limit. These updates align rounding practices across laboratories and reinforce existing expectations without adding new regulatory requirements.

Adding new criteria for determining when a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails testing for total CBD based on exceeding the relative percent difference (RPD) or relative standard deviation (RSD). Under the new criteria, items containing at least 10.0 milligrams (mg) but less than 50.0 mg of total CBD would fail if the RPD or RSD exceeds 50.0%. Items that fail under this provision may be remediated through re-mixing. Increasing the RPD and RSD limits for cannabinoid concentrates, extracts, finished inhalable cannabinoid products, or industrial hemp-derived vapor items with low levels of CBD maintains sufficient homogeneity and consistency across samples and allows a practical level of variation that is expected to minimally affect product quality or safety of the item. Low concentration of CBD is not known to be intoxicating or to enhance or modify the effects of THC potency. Additionally, this proposed change targets high THC items which typically contain low levels of CBD. Establishing a CBD-specific RPD/RSD threshold for these items therefore provides a more practical measure of consistency. This amendment is expected to reduce product failures driven by minor variations in low-level CBD content. The amendment is expected to reduce product loss and associated financial impacts for cannabis processors while maintaining a satisfactory level of product uniformity and consumer protection.

Clarifications are also proposed for the measurement of the pesticides Abamectin and Spinosad. For Abamectin, the rule would specify that it must be quantified as the combined residue of avermectin B1a and B1b, reflecting the compound's actual composition and aligning with federal standards. For Spinosad, the rule would specify measurement as the cumulative residues of Spinosyn A and Spinosyn D. These updates improve accuracy, reduce false reporting, and align testing methods with established federal approaches. The changes provide clearer directions to laboratories without adding new compliance burdens. Although research on pesticide exposure through cannabis consumption is still limited, inhaling pesticide residues may increase toxicity and contribute to respiratory or other health concerns. These proposed rule changes help ensure more accurate testing and support consumer safety.

Language is added to clarify that if any individual sample increment exceeds the maximum concentration limits allowed under OLCC rules, the product fails for potency. This clarifying language had been inadvertently removed during a previous rule change. Restoring it supports public health and safety by ensuring cannabinoid products remain within allowable concentration limits, and by confirming that a product fails if even one tested sample exceeds the limit, even when the mean (average) of two samples is within compliance. This update also resolves prior inconsistencies in how laboratories determined concentration limit failures, promoting clearer and more consistent application of the rule.

The following is a summary of division 64 changes.

One proposed change broadens options for proficiency testing (PT) providers to allow ISO / IEC 17043 PT providers who are approved by the Oregon Environmental Laboratory Accreditation Program (ORELAP). This change increases PT provider choice and is equivalent to PT requirements in other states where cannabis is regulated.

Other changes would improve measurement accuracy and precision of potency and contaminants. For psilocybin, this includes changing the definition and calculation for "total potential psilocin" to "total psilocybin equivalent". This also includes updating the definition of "homogenization". Homogenization makes the sample uniform in composition through particle size reduction. Fresh or dried plant material, such as marijuana or usable marijuana, is not uniform or

homogenous in its original form.

Additionally, the proposed rules add a maximum particle size of 1 millimeter (mm) for homogenized marijuana and usable marijuana and requirement to perform an initial validation study for the homogenization process. The laboratory must mix the homogenized sample and ensure a representative portion of the homogenized sample is used for compliance tests. The particle size of 1 mm reduces measurement uncertainty and increases extraction efficiency. The requirement helps to minimize the uncertainty of testing results and protect public health and safety through better precision and accuracy of test results for potency and contaminants, including but not limited to pesticides. The proposed changes clarify rules regarding homogenization to state that stems and leaf material are not to be removed prior to homogenization. This is an existing rule requirement and the proposed changes are a clarification and not a change in requirements. Ensuring stems and leaf material are included in the homogenization procedure for marijuana and usable marijuana increases the accuracy of testing for metals, and systemic pesticides, including but not limited to metalaxyl and myclobutanil. These clarifications and changes to the homogenization procedure of marijuana and usable marijuana protect public safety because they improve sample characterization, extraction efficiency, and reduce measurement uncertainty, which will ensure more precise and accurate results. The updates to homogenization rules will be effective March 1, 2027, although existing requirements already require some of the requirements being clarified.

Other changes will be implemented to strengthen analytical method validity and quality control. One of these changes is adding quality control acceptance criteria to initial calibration verification (ICV) and continuing calibration verification (CCV) to the acceptance limits in OAR 333-064-0100 Exhibit C, Table 1 and OAR 333-064-0140 Exhibit D, Table 1. Additionally, water activity will be added to the analyte list in OAR 333-064-0100 Exhibit C to add quality control limits for ICV and CCV. Another change to improve analytical quality control is placing criteria around the characterization of laboratory control samples (LCS) for potency testing. Additionally, the change of adding trailing zeros to limits will be used to ensure significant figures are expressed consistently.

Other proposed changes will enhance data integrity, transparency, and standardize data handling. These changes include adding a requirement that rounding may only occur at the end of calculations, adding limit of quantitation (LOQ) requirements for the individual analytes THC and THC-A, rather than only Total THC, adding a list of prohibited laboratory activities and a requirement that laboratories train their personnel to not conduct those prohibited activities, adding information that must be listed on test reports, and adding steps laboratories must follow if an error entered into the cannabis tracking system (CTS) is discovered after reporting. The required changes impacting marijuana and usable marijuana homogenization procedure and what must be listed on reports will be effective after March 1, 2027.

Overall, these changes protect public health and consumer safety by improving the accuracy of potency labeling and enhancing clarity in contaminant testing measurements. More precise results support informed purchasing decisions, increase confidence in product consistency, and reduce the risk of mislabeled potency or under reported pesticide residues. This helps to prevent marijuana items that have potentially harmful contaminants from being sold to consumers.

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#### DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS chapter 475C: [https://www.oregonlegislature.gov/bills\\_laws/ors/ors475c.html](https://www.oregonlegislature.gov/bills_laws/ors/ors475c.html)

Oregon Administrative Rules, Chapter 845, Division 25 – Recreational Marijuana:

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3873>

Oregon Administrative Rules, Chapter 845, Division 26 – Adult Use Cannabis and Hemp Concentration Limits

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=6492>

National Institute of Standards and Technology, CannaQAP Final Report:

<https://nvlpubs.nist.gov/nistpubs/ir/2024/NIST.IR.8519.pdf>

Code of Federal Regulations for Abamectin:

<https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.449>

EPA Memorandum on Abamectin: Preliminary Ecological Risk Assessment for Registration Review:

<https://downloads.regulations.gov/EPA-HQ-OPP-2013-0360-0031/content.pdf>

Code of Federal Regulations for Spinosad:

<https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.495>

Cytotoxic effects of bio-pesticide Spinosad on human lung A549 cells:

<https://www.sciencedirect.com/science/article/pii/S00455653519309397>

FDA Investigation Out-Of-Specification (OOS) Test Results for Pharmaceutical Production Guidance for Industry (May 2022): <https://www.fda.gov/media/158416/download>

21 CFR Part 111: Current good manufacturing practice in manufacturing, packaging, labeling, or holding operations for dietary supplements: <https://www.ecfr.gov/current/title-21/part-111>

2016 TNI Standard: <https://nelac-institute.org/content/CSDP/standards.php>

40 CFR 1090.50 Regulation of Fuels, Fuel Additives, and Regulated Blendstocks Rounding:

<https://www.ecfr.gov/current/title-40/section-1090.50>

American Council of Independent Laboratories (ACIL) Guide to Harmonizing Cannabis

Laboratory Quality and Testing Practices (Effective January 2023):

<https://cdn.ymaws.com/www.acil.org/resource/resmgr/cannabis/2023-1-Guide-to-Harmonizing-.pdf>

Angelova, S., & Gjorgjeska, B. (2022). The role of cannabis flower sampling in quality control in medical cannabis industry: A review. *Knowledge – International Journal*, 53(4), 683–686. To receive a copy, email [ORELAP.INFO@odhsoha.oregon.gov](mailto:ORELAP.INFO@odhsoha.oregon.gov)

Atkins, Patricia L. "Sample Processing and Preparation Considerations for Solid Cannabis Products." *Journal of AOAC International*, vol. 102, no. 2, 2019, pp. 427–433. <https://doi.org/10.5740/jaoacint.18-0203>

American Society for Testing and Materials (ASTM) D8493-23 Standard Guide for Sample Preparation of Cannabis and Hemp Inflorescence for Laboratory Analysis: <https://store.astm.org/d8493-23.html>

Bode, Gwen. "Back to the Root-The Role of Botany and Plant Physiology in Cannabis Testing, Part II: Plant-Pesticide Interactions and Plant Defense." *Cannabis Science and Technology*, vol. 3, no. 4, 12 May 2020, <https://www.cannabissciencetech.com/view/back-root-role-botany-and-plant-physiology-cannabis-testing-part-ii-plant-pesticide>

California Department of Cannabis Control. (2025). Approved Text of Regulations—Standard Cannabinoids Test Method and Standardized Operating Procedures. [https://cdn.cannabis.ca.gov/wp-content/uploads/sites/2/2025/11/approved\\_text\\_standard\\_test\\_methods\\_operating\\_procedures.pdf](https://cdn.cannabis.ca.gov/wp-content/uploads/sites/2/2025/11/approved_text_standard_test_methods_operating_procedures.pdf)

Loffredo E, Picca G, Parlavecchia M. Single and combined use of Cannabis sativa L. and carbon rich materials for the removal of pesticides and endocrine disrupting chemicals from water and soil. *Environ Sci Pollut Res Int*. 2020;28(3):3601–3616. doi:10.1007/s11356-020-10690-7: <https://link.springer.com/article/10.1007/s11356-020-10690-7>

Warneke, B., Pscheidt, J. W., & Nackley, L. Pesticide Redistribution and Its Implications on Pesticide Efficacy. OSU Extension Service, PNW 772, March 2023. Available at: <https://extension.oregonstate.edu/catalog/pub/pnw-772-pesticide-redistribution-its-implications-pesticide-efficacy>

Official Methods of Analysis of AOAC INTERNATIONAL (2023), 22nd Ed., AOAC INTERNATIONAL, Rockville, MD, USA, Method 2018.11, <https://academic.oup.com/aoac-publications>

EPA method 200.8 Determination of Trace Elements in Waters and Wastes by Inductively Coupled Plasma – Mass Spectrometry Revision 5.4: <https://www.epa.gov/sites/default/files/2015-06/documents/epa-200.8.pdf>

ISO / IEC 17043: <https://www.iso.org/standard/80864.html>

Oregon Liquor and Cannabis Commission (OLCC) Technical Report: Evaluating Compliance, Potency, and Pesticides in Oregon’s Marijuana and Hemp Markets Ten Years after Legalization (May 2025): <https://olis.oregonlegislature.gov/liz/2026R1/Downloads/PublicTestimonyDocument/243663>

Oregon Psilocybin Services (OPS) – 2026 Psilocybin Product Potency Workgroup: <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Psilocybin-2026-Potency-Workgroup.aspx>

Rheay, H.T., Omondi, E.C. and Brewer, C.E. (2021), Potential of hemp (Cannabis sativa L.) for paired phytoremediation and bioenergy production. *GCB Bioenergy*, 13: 525-536. <https://doi.org/10.1111/gcbb.12782>

U.S. Environmental Protection Agency, Office of Pesticide Programs, Registration Division. (2024, April 29). MYCLOBUTANIL 20EW AG: Pesticide product label (EPA Reg. No. 42750 165). [https://www3.epa.gov/pesticides/chem\\_search/ppls/042750-00165-20240429.pdf](https://www3.epa.gov/pesticides/chem_search/ppls/042750-00165-20240429.pdf)

Standard Methods (SM) Committee of the American Public Health Association, American Water Works Association, and Water Environment Federation. 1050 Expression of Results In: Standard Methods For the Examination of Water and Wastewater. Lipps WC, Baxter TE, Braun-Howland E, editors. Washington DC: APHA Press. DOI: 10.2105/SMWW.2882.008 <https://www.standardmethods.org/doi/10.2105/SMWW.2882.008>

The NELAC Institute (TNI) Standard Draft of Volume 1 Module 2 Management and Testing Requirements for Laboratories Performing Environmental Analysis Quality Management System Requirements (posted May 2026): <https://nelac-institute.org/docs/standards/2026/DS-EL-V1M2-20260514-FINAL.pdf>

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#### STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE:

This rulemaking is a collaboration between the Oregon Medical Marijuana Program (OMMP) and the Oregon

Environmental Laboratory Accreditation Program (ORELAP). Both programs are a part of the Oregon Health Authority, Public Health Division. This equity impact statement addresses both the testing standards being updated by OMMP, and the enhanced operational process for laboratories being implemented by ORELAP. The proposed amendments primarily modernize and clarify cannabis and psilocybin testing rules and also reduce regulatory barriers and improve consistency in product safety standards. They indirectly advance equity by improving clarity, reducing compliance burden, and strengthening product safety within Oregon's cannabis and psilocybin regulatory system.

Clarified testing thresholds for contaminants and potency improve consumer safety and transparency across all communities while also reducing administrative and financial burdens for smaller cannabis businesses. Clearer testing thresholds ensure safer and accurately labeled products across all communities, helping to reduce disparities in exposure to unregulated or lower quality cannabis products. The rules are not changing any action limits for contaminant testing; they are creating more accuracy in how laboratories test for them. These benefits will have a greater impact on vulnerable populations like those enrolled in the medical marijuana program who use cannabis to help with their debilitating health condition or those who access services through Oregon Psilocybin Services (OPS) licensed businesses.

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#### FISCAL AND ECONOMIC IMPACT:

The proposed rule amendments are expected to have minimal fiscal and economic impact on OMMP registrants, OLCC licensees, hemp, cannabis and psilocybin testing laboratories, state agencies, Oregon Psilocybin Services (OPS) customers, and cannabis consumers. The amendments in division 7 rely on existing testing systems and require little to no additional equipment, staffing, or state resources.

Some amendments are anticipated to produce net economic savings for businesses. Under current rules, batches that fall outside the intended target potency, but still meet OLCC concentration limits cannot be retested, which may result in unnecessary disposal of compliant products or costly re-labeling of the item. Avoiding disposal of a batch or requiring the need to re-label a product without first confirming through testing the potency result can preserve hundreds to thousands of dollars in product value, depending on batch size and production cost. In comparison, a \$40-\$75 re-analysis testing represents a substantially lower cost, making re analysis a cost effective alternative to discarding otherwise compliant inventory, or re-labeling it, and potentially mis-labeling a product. In addition, increasing RPD/RSD limits for low-level CBD cannabinoid concentrate, extract, finished inhalable cannabinoid product, and industrial hemp-derived vapor items is expected to decrease costs for cannabis processors by reducing the number of products that fail testing due to minimal variability in low level CBD content. Allowing remediation through re mixing is expected to further minimize product loss and reduce fiscal losses for processors. No significant fiscal impact is anticipated for testing laboratories or regulatory agencies, and the rule is not expected to have an adverse effect on small businesses or the public.

Clarifying pesticide quantification requirements and action levels is expected to reduce false failures, re-testing, and misreported results. This increases testing consistency between laboratories and reduces the risk of costly corrective actions, relabeling, or product recalls. Laboratory costs associated with adopting the clarified measurement standards are expected to be minimal and absorbed into normal validation processes. It is unknown if there will be more failures seen due to this change which could result in a loss for licensees. Most, if not all laboratories are already able to quantify Abamectin and Spinosad in the manner that is being proposed.

The proposed changes to division 64 will primarily be experienced by cannabis, hemp, and psilocybin testing laboratories. Members of the public and other entities may also experience fiscal and economic impact if the cost of items tested by

laboratories increases in response to these rule changes.

For adding additional ORELAP-approved ISO / IEC 17043 proficiency test (PT) providers, if a laboratory chooses to use one of these PT providers, the cost of those PTs may be greater than the cost of PTs by current The NELAC Institute (TNI) Standard approved PT providers. Laboratories may still opt to use the current TNI Standard approved PT providers and are not required to use the new options for PT providers.

ORELAP anticipates no fiscal impact due to the clarification of existing requirements on homogenization of marijuana or usable marijuana because the requirement to test the sample as received and ensure the sample is representative of the batch is an existing requirement.

A fiscal impact may be felt by laboratories from the compliance requirements to do a one-time validation of homogenization procedures for marijuana or usable marijuana, as the laboratories may need to purchase a 1 millimeter (mm) sieve to perform the validation or purchase additional homogenization equipment to meet the new requirements. This validation study will also require staff time and planning. A fiscal impact may be felt by laboratories to ensure samples, particularly larger mass samples, meet the homogenization requirements for marijuana or usable marijuana. Laboratories that process larger mass samples may incur ongoing costs related to increased labor time, additional consumables, or equipment wear resulting from meeting the revised homogenization requirements.

A fiscal impact may be felt by laboratories by adding the acceptance criteria requirements for initial calibration verification (ICV) and continuing calibration verification (CCV). Laboratories that need to update test methods may face costs associated with documentation changes, retraining, or method development. Additional calibration steps, troubleshooting, or re-analysis for analytical batches that do not have acceptable ICV or CCV results could increase per-batch operating costs. Laboratories may have an increased cost for performing new required steps for characterizing laboratory control samples (LCS) for potency testing, including preparation materials and analyst time.

Laboratories may experience a fiscal impact for updating their internal processes to meet the requirements for changing the calculation for “total potential psilocin” to “total psilocybin equivalent”, adding trailing zeros to acceptance criteria limits and action limits, updating test reports to ensure compliance with updated reporting regulations, and additional administrative and quality assurance steps to implement if an error is discovered after reporting. These activities may require software updates, staff training, and increased time for data review, each of which contributes to operational cost. OHA is unable to determine a specific dollar amount due to the multi-faceted potential impact by the proposed rule changes.

The fiscal impacts associated with these rule amendments vary by laboratory scale, testing volume, and current equipment capabilities. These proposed rule amendments support improved consistency, accuracy, and regulatory compliance in laboratory testing activities.

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#### COST OF COMPLIANCE:

*(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).*

(1) The amendments do not introduce new fees, or enforcement mechanisms. The amendments require ORELAP to create a program for approving new ISO / IEC 17043 accredited proficiency test (PT) providers and Oregon Liquor and Cannabis Commission (OLCC) may need to make updates to the Cannabis Tracking System (CTS). Existing compliance

and oversight structures are sufficient to implement the rule changes, resulting in negligible fiscal impact on the Oregon Health Authority (OHA), OLCC, Oregon Psilocybin Services (OPS) or other state partners. The public may be impacted by increased costs for services if laboratory fees increase for registrants and licensees and increased costs are passed to consumers as a result of these rules.

(2)(a) There are about 9 cannabis testing laboratories. Other marijuana and hemp market participants that may be impacted by this rule include, 265 OLCC licensed processors, 1356 OLCC licensed producers, 761 OLCC licensed retailers, and 235 OLCC licensed wholesalers. There are about 21 OLCC licensed hemp growers and handlers certified.

There are about 101 Oregon Department of Agriculture (ODA) licensed hemp growers and about 141 ODA licensed hemp handlers.

It is estimated that up to 6,000 businesses may require a hemp vendor license and that the majority would qualify as small businesses (<https://records.sos.state.or.us/ORSOSWebDrawer/Recordhtml/10086706>).

Hemp items are also required to be registered with the OLCC. A hemp product registration is required for each unique product, rather than a business, and it makes it difficult to estimate the number of small businesses subject to hemp product registration and potentially impacted by these rules. In addition, it is difficult to accurately ascertain the full scope of small businesses impacted because the hemp registry's requirements apply to out-of-state businesses as well and there are no national registration or licensing requirements for businesses that manufacture, distribute, or sell hemp products.

There are currently no registered OMMP dispensaries or processing sites. While medical growers do not fit the definition of a small business, there are approximately 2057 growers registered with the program.

There are currently 379 Oregon Psilocybin Services (OPS) licensed facilitators, 1 licensed OPS laboratory, 7 licensed OPS manufacturers, and 20 licensed OPS service centers.

(b) A registrant or licensee may be required to undertake occasional administrative activities regarding needing to review processes followed during manufacturing of a product prior to requesting a re analysis for missing their target potency but are expected to benefit from reduced waste, more reliable labeling, and lower risk of market disruptions due to testing outcomes.

There may be minimal added costs for laboratories associated with clarifying action limits by adding a trailing zero. The systems they use to produce results and certificate of analysis may need adjusting to comply with this rule change and would end up being a one-time upfront cost. OPS licensed businesses may incur cost for changing labels from 'total potential psilocin' to 'total psilocybin equivalent'.

Laboratories may incur administrative costs to update their laboratory information management systems (LIMS) to meet the new requirements. Additional staff time for training, documentation updates, and quality assurance review processes may increase administrative costs.

OHA is unable to determine the specific dollar amount due to the unique circumstances of each business subject to or affected by the proposed rule changes and the multi-faceted potential impact of the proposed rule changes.

(c) Proposed changes under division 7 could impact labor and increased administration for compliance for registrants and licensees if a target potency is not met and they need to investigate their processes, but labor impacts are expected to be minimal. A processor may need limited staff time to review production records and confirm adherence to

established protocols before requesting a re-test.

Laboratories may incur costs for equipment, supplies, labor or increased administration to comply with the proposed rules for division 64. Such changes include updating procedures or purchasing equipment to be in compliance with new homogenization requirements for usable marijuana, additional testing of laboratory control samples (LCS) when performing new characterization requirements, updating procedures or performing troubleshooting to meet new initial calibration verification (ICV) and continuing calibration verification (CCV) requirements, administrative costs to updating reports and performing additional steps when correcting an error that is discovered by the laboratory. Laboratories may pay more for using newly approved proficiency test (PT) providers, but this is optional and laboratories may still use the currently approved PT providers. It is difficult to ascertain the full scope of the fiscal impacts to laboratories associated with these rule amendments as they may vary depending on laboratory scale, testing volume, and current equipment capabilities.

OHA is unable to determine a specific dollar amount due to the unique circumstances of each business subject to or affected by the proposed rule changes and the multi-faceted potential impact of the proposed rule changes.

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#### DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

OHA held Rules Advisory Committee (RAC) meetings to assist in the development of these proposed rules. The RAC included small businesses who are licensed by the OLCC such as producers, processors, wholesalers, and laboratories. In addition, two members from the Cannabis Industry Alliance of Oregon (CIAO) were involved in the rulemaking process and provided feedback. CIAO is a member-driven non-profit that advocated for over 500 cannabis licenses statewide and represent every type of Oregon Liquor and Cannabis Commission (OLCC) license type. The rulemaking also had representation from two Oregon Psilocybin Services (OPS) licensees, Oregon Medical Marijuana Program (OMMP) patients, and public members.

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#### WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

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#### RULES PROPOSED:

333-007-0310, 333-007-0315, 333-007-0320, 333-007-0330, 333-007-0341, 333-007-0342, 333-007-0350, 333-007-0360, 333-007-0400, 333-007-0410, 333-007-0415, 333-007-0420, 333-007-0425, 333-007-0430, 333-007-0450, 333-007-0600, 333-064-0025, 333-064-0100, 333-064-0110, 333-064-0120, 333-064-0140, 333-064-0150

AMEND: 333-007-0310

RULE SUMMARY: OAR 333-007-0310: Amending rule to add a new definition for "target potency".

#### CHANGES TO RULE:

333-007-0310

Definitions ¶

For purposes of OAR 333-007-0300 through 333-007-0500:¶

(1) "Added substance" means any component or ingredient added to usable marijuana, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the finished cannabinoid product, including but not limited to flavors, non-marijuana derived terpenes, and any substances used to change the viscosity or consistency of the cannabinoid product.¶

(2) "Adult use cannabinoid" includes, but is not limited to, tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, the optical isomers of delta-8-tetrahydrocannabinol or delta-9-tetrahydrocannabinol and any artificially derived cannabinoid

that is reasonably determined to have an intoxicating effect.¶¶

(3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae.¶¶

(b) "Artificially derived cannabinoid" does not include:¶¶

(A) A naturally occurring chemical substance that is separated from the plant Cannabis family Cannabaceae by a chemical or mechanical extraction process;¶¶

(B) Cannabinoids that are produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst; or¶¶

(C) Any other chemical substance identified by the ~~Commission, in consultation with the Authority~~Oregon Liquor and Cannabis Commission (Commission), in consultation with the Oregon Health Authority (Authority) and the Department of Agriculture, by rule.¶¶

(4) "Authority" means the Oregon Health Authority.¶¶

(5) "Batch" means:¶¶

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

(b) A quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.¶¶

(6) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.¶¶

(7) "Cannabinoid capsule":¶¶

(a) Means a small soluble pill, tablet, or container that contains liquid or powdered cannabinoid product, concentrate, or extract and is intended for human ingestion.¶¶

(b) Does not mean a cannabinoid suppository.¶¶

(8) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.¶¶

(9) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.¶¶

(10)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana; or¶¶

(b) Usable marijuana, cannabinoid extracts and cannabinoid concentrates that have been combined with an added substance.¶¶

(c) "Cannabinoid product" does not include:¶¶

(A) Usable marijuana by itself;¶¶

(B) A cannabinoid concentrate or extract by itself; or¶¶

(C) Industrial hemp.¶¶

(11) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina, containing a cannabinoid product, concentrate or extract.¶¶

(12) "Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of four fluid ounces or less that consists of either:¶¶

(a) A non-potable solution consisting of at least 25 percent non-denatured alcohol, in addition to cannabinoid concentrate, extract or usable marijuana, and perhaps other ingredients intended for human consumption or ingestion that is exempt from the Liquor Control Act under ORS 471.035; or¶¶

(b) A non-potable solution comprised of glycerin, plant-based oil, or concentrated syrup; cannabinoid concentrate, extract or usable marijuana; and perhaps other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.¶¶

(13) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes a cannabinoid transdermal patch.¶¶

(14) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.¶¶

(15) "Cannabis" means the plant species Cannabis sativa and in these rules refers to all forms of the plant regardless of total delta-9-THC content and may also be used to refer to processed products that contain marijuana or industrial hemp.¶¶

(16) "Cannabis reference laboratory" means the Oregon Department of Agriculture cannabis testing laboratory.¶¶

(17) "Cannabis Tracking System" or "CTS" means the Oregon Liquor and Cannabis Commission's system for tracking the transfer of marijuana items or industrial hemp-derived vapor item and other information as authorized by ORS 475C.177.¶¶

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

(19) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.¶¶

(20) "Commission" means the Oregon Liquor and Cannabis Commission.¶¶

(21) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a

marijuana item or industrial hemp-derived vapor item.¶¶

(22) "Consumer" has the meaning given that term in ORS 475C.009 and does not include a patient, designated primary caregiver or organization or facility caregiver.¶¶

(23) "Cured" means a process of removing moisture from marijuana under controlled environmental conditions so the moisture content is 15 percent or less.¶¶

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

(25) "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.¶¶

(26) "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.¶¶

(27)(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475C.783(5)(b).¶¶

(b) "Designated primary caregiver" does not include the person's attending physician.¶¶

(28) "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 or industrial hemp-derived vapor item being sampled that is prepared and analyzed separately from the primary sample.¶¶

(29) "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.¶¶

(30) "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.¶¶

(31) "Finished inhalable cannabinoid product" means a cannabinoid product that is intended for human use via inhalation, 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.¶¶

(32) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, chewing gum and includes beverages.¶¶

(33) "Grow site" means a specific location registered by the Authority and used by the grower to produce marijuana for medical use by a specific patient under ORS 475C.792.¶¶

(34) "Grower" has the same meaning as "person responsible for a marijuana grow site."¶¶

(35) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a seven calendar-day period at the same location and cured under uniform conditions.¶¶

(36) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.¶¶

(37) "Human consumption or human ingestion" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.¶¶

(38) "Human use" includes human consumption or human ingestion, inhalation, topical application or any other use that allows a cannabinoid to enter the human body.¶¶

(39) "Industrial hemp" has the meaning given that term in ORS 571.269.¶¶

(40) "Industrial hemp-derived vapor item" means an industrial hemp concentrate or industrial hemp extract, as those terms are defined in ORS 571.269, whether alone or combined with other substances, that is intended for use in an inhalant delivery system.¶¶

(41) "Inhalant delivery system" has the meaning given that term in ORS 431A.175.¶¶

(42) "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 and Cannabis Commission under ORS 475C.548.¶¶

(43) "Licensee" has the meaning given that term in ORS 475C.009.¶¶

(44)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.¶¶

(b) "Marijuana" does not include industrial hemp.¶¶

(45) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.¶¶

(46) "Marijuana processing site" means a marijuana processing site registered under ORS 475C.815.¶¶

(47) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475C.833.¶¶

(48) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the

Authority pursuant to ORS 438.605 to 438.620.¶

(49) "Organization or facility caregiver" means:¶

(a) An organization that provides hospice, palliative or home health care services that:¶

(A) Is licensed under ORS 443.014 to 443.105, 443.305 to 443.355, or 443.850 to 443.869;¶

(B) Has significant responsibility for managing the well-being of a patient; and¶

(C) Is designated by the Authority as an additional caregiver for a patient; or¶

(b) A residential facility as defined in ORS 443.400 that:¶

(A) Is licensed under ORS 443.400 to 443.455;¶

(B) Has significant responsibility for managing the well-being of a patient: and¶

(C) Is designated by the Authority as an additional caregiver for a patient.¶

(50) "Patient" has the same meaning as "registry identification cardholder."¶

(51) "Person responsible for a marijuana grow site" has the same meaning as "grower" and means a person who has been selected by a patient to produce medical marijuana for the patient and who has been registered by the Authority for this purpose under ORS 475C.792.¶

(52) "Process lot" means:¶

(a) Any amount of cannabinoid concentrate or extract or industrial hemp-derived vapor item of the same type that is homogeneous 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.¶

(53) "Processing" means:¶

(a) The compounding or conversion of marijuana into cannabinoid products, or cannabinoid concentrates or extracts.¶

(b) The compounding or conversion of industrial hemp into industrial hemp concentrates or industrial hemp extracts.¶

(54) "Processing site" means a processor registered with Authority under ORS 475C.815.¶

(55) "Processor" means a marijuana processor, as that term is defined in ORS 475C.009, that holds a license issued under ORS 475C.085.¶

(56) "Producer" has the meaning given that term in OAR 845-025-1015.¶

(57) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475C.792, 475C.815 or 475C.833.¶

(58) "Registry identification cardholder" means a person who has been diagnosed by an attending physician with a debilitating medical condition and for whom the use of medical marijuana may mitigate the symptoms or effects of the person's debilitating medical condition, and who has been issued a registry identification card by the Authority under ORS 475C.783(5)(a).¶

(59) "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100.¶

(60) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.¶

(61) "Remediation":¶

(a) Means a process or technique applied to a marijuana item or industrial hemp-derived vapor item to remove, destroy, or eliminate heavy metals, pesticides, microbiological contaminants, or solvents.¶

(b) Does not include dilution.¶

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

(63) "Sample" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.¶

(64) "Sample increment" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing.¶

(65) "Standard operating procedure" means:¶

(a) A written set of instructions or procedures using the same ingredients, methods and steps to create a single type of marijuana item or industrial hemp-derived vapor item.¶

(b) For the purposes of producing kief includes but is not limited to procedures for creating the kief, purging unwanted components from the kief, thoroughly cleaning all equipment, counters and surfaces used to produce the kief, and appropriate use of any necessary safety or sanitary equipment.¶

(66) "Sterilization" means the removal, destruction, or elimination of all microorganisms and other pathogens from a marijuana item or industrial hemp-derived vapor item by treating it with approved chemicals, subjecting it to a temperature exceeding 180 degrees Fahrenheit, or other process.¶

(67) "Target potency" has the meaning given to that term in OAR 845-025-7000.¶

(68) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.¶

(68) "Texture" means the feel, appearance, or consistency of a marijuana item or industrial hemp-derived vapor item.¶

(69) "These rules" means OAR 333-007-0300 through 333-007-0500.¶

(70) "Total CBD" means the sum of the concentration or mass of CBDA multiplied by 0.877 plus the concentration or mass of CBD.¶

(71) "Total delta-9-THC" means the sum of the concentration or mass of delta-9-THCA multiplied by 0.877 plus the concentration or mass of delta-9-THC.¶

(72) "Unit of sale" means an amount of a marijuana item or industrial hemp-derived vapor item commonly packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver, or capable of being packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver.¶

(73) "Usable marijuana":¶

(a) Means the dried leaves and flowers of marijuana.¶

(b) Includes, for purposes of these rules, pre-rolled marijuana as long as the pre-roll consists of only dried marijuana leaves and flowers, an unflavored rolling paper and a filter or tip.¶

(c) Does not include:¶

(A) The seeds, stalks and roots of marijuana; or¶

(B) Waste material that is a by-product of producing or processing marijuana.

Statutory/Other Authority: ORS 475C.544, ORS 475C.540

Statutes/Other Implemented: ORS 475C.544, ORS 475C.540

RULE SUMMARY: OAR 333-007-0315: Amending rule to clarify for cannabinoid products that the weight or mass of all serving sizes the item intends to have must be provided to the laboratory upon ordering a test. Also adding a new section around target potency, which would be optional, for cannabinoid products.

CHANGES TO RULE:

333-007-0315

Ordering Tests ¶¶

(1) To request a compliance test a requestor must provide a laboratory, prior to laboratory taking samples, with at a minimum, the following information as applicable:¶¶

(a) The registrant or licensee's registrant or license number.¶¶

(b) The name, address and contact information of the registrant or licensee.¶¶

(c) If a registrant, whether the registrant is subject to tracking in the Cannabis Tracking System (CTS), under OAR chapter 333, division 8.¶¶

(d) Type of marijuana item or industrial hemp-derived vapor item.¶¶

(e) Harvest lot number that is associated with the batch numbers, if applicable.¶¶

(f) Process lot number that is associated with the batch numbers, if applicable.¶¶

(g) Batch numbers to be sampled.¶¶

(h) Total mass or volume of each batch to be sampled.¶¶

(i) For cannabinoid products, all intended units of sale, the weight or mass of all intended serving sizes and units of sale. For cannabinoid products in liquid form, also include:¶¶

(A) The density of the product; or¶¶

(B) The volume of all intended serving sizes and units of sale.¶¶

(j) Identification of the test or tests the laboratory is being requested to conduct.¶¶

(k) Whether the test or tests being requested are compliance tests.¶¶

(l) Whether the test or tests being requested are for quality control, research and development, or any other purpose other than a compliance test.¶¶

(m) Whether a batch is being re-sampled because of a failed test, the date the failed test result was received by the registrant or licensee and laboratory identification number of the laboratory that conducted the initial test.¶¶

(n) Whether the marijuana item or industrial hemp-derived vapor item was remediated if remediation is permitted under OAR 333-007-0450.¶¶

(o) If a wholesaler is requesting a test on behalf of another registrant or licensee, the wholesaler must provide in addition to their own license number and name, the registration or license number and name of that registrant or licensee.¶¶

(2) If the registrant or licensee informs a laboratory that a marijuana item or industrial hemp-derived vapor item is being re-sampled after a failed test, the registrant or licensee must provide the laboratory with documentation of the failed test as applicable.¶¶

(3) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.¶¶

(4) A registrant or licensee may only order a compliance test for a marijuana item that the registrant or licensee has produced or processed, as applicable, except a wholesaler who may order a compliance test.¶¶

(5) More than one compliance test for the same marijuana item or industrial hemp-derived vapor item may not be ordered.¶¶

(6) It is a violation of these rules for a registrant or licensee to:¶¶

(a) Fail to provide the information required in these rules to the laboratory; or¶¶

(b) Submit false or misleading information to a laboratory or a directed agent to submit false or misleading information to a laboratory.¶¶

(7) Once a test order has been submitted to a laboratory by a registrant or licensee and at least one test has already been performed, the order may not be canceled unless written permission is given by the Oregon Liquor and Cannabis Commission, the Oregon Health Authority or the Department of Agriculture.¶¶

(8) A registrant or licensee that requests testing on a cannabinoid product may provide to the laboratory, prior to laboratory taking samples, the target potency per serving or per container of any cannabinoid listed under OAR 333-007-0430(1) in the item being tested for the purpose of establishing an additional failure criteria as described in OAR 333-007-0430(4).

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0320

RULE SUMMARY: OAR 333-007-0320: Amends rule to remove language tied to a past date.

CHANGES TO RULE:

333-007-0320

Compliance Testing Requirements for Marijuana or Usable Marijuana ¶

(1) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a consumer or patient prior to selling or transferring the marijuana or usable marijuana for the following:¶

(a) Pesticides in accordance with OAR 333-007-0400.¶

(b) Water activity and moisture content in accordance with OAR 333-007-0420.¶

(c) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.¶

(d) Heavy metals in accordance with OAR 333-007-0415 ~~if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.~~¶

~~(e) Mycotoxins in accordance with OAR 333-007-0425 if the marijuana or usable marijuana is or was harvested on or after July 1, 2022.~~¶

~~(f) Microbiological contaminants in accordance with OAR 333-007-0390 if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.~~¶

~~(2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana harvested before March 1, 2023, intended for use by a processor or processing site in making a cannabinoid concentrate, extract, or finished inhalable cannabinoid product for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.~~¶

~~(3.)~~

(e) Mycotoxins in accordance with OAR 333-007-0425.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390.¶

(2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid product, except for a finished inhalable cannabinoid product, for the following:¶

(a) Pesticides in accordance with OAR 333-007-0400.¶

(b) Water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.¶

(c) Heavy metals in accordance with OAR 333-007-0415 ~~if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.~~¶

~~(d) Mycotoxins in accordance with OAR 333-007-0425 if the marijuana or usable marijuana is or was harvested on or after July 1, 2022.~~¶

~~(e) Microbiological contaminants in accordance with OAR 333-007-0390 if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.~~¶

(d) Mycotoxins in accordance with OAR 333-007-0425.¶

(e) Microbiological contaminants in accordance with OAR 333-007-0390.¶

(43) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission Oregon Liquor and Cannabis Commission (Commission) under ORS 475C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶

(5) A marijuana producer must test every batch from a harvest lot of marijuana or usable marijuana harvested before March 1, 2023 intended to produce kief for water activity prior to producing the kief unless the producer tests the kief for water activity per OAR 333-007-0420.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0330

RULE SUMMARY: OAR 333-007-0330: Amends rule language to remove language tied to a past date and update a grammatical issue that doesn't change the context of the rule.

CHANGES TO RULE:

333-007-0330

Compliance Testing Requirements for Cannabinoid Concentrates and Extracts ¶¶

(1) A processor or processing site must test every process lot of a finished cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following:¶¶

(a) Pesticides in accordance with OAR 333-007-0400.¶¶

(b) Solvents in accordance with OAR 333-007-0410.¶¶

(c) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.¶¶

(d) Heavy metals in accordance with OAR 333-007-0415 ~~if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.~~¶¶

(e) ~~Mycotoxins in accordance with OAR 333-007-0425 if the cannabinoid concentrate or extract is or was manufactured on or after July 1, 2022.~~¶¶

(f) ~~Microbiological contaminants in accordance with OAR 333-007-0390 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.~~¶¶

(e) Mycotoxins in accordance with OAR 333-007-0425.¶¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390.¶¶

(2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product, other than a finished inhalable cannabinoid product, for the following, except for a cannabinoid concentrate that meets the criteria in section (5) of this rule:¶¶

(a) Pesticides in accordance with OAR 333-007-0400.¶¶

(b) Solvents in accordance with OAR 333-007-0410.¶¶

(c) Heavy metals in accordance with OAR 333-007-0415 ~~if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.~~¶¶

(d) ~~Mycotoxins in accordance with OAR 333-007-0425 if the cannabinoid concentrate or extract is or was manufactured on or after July 1, 2022.~~¶¶

(e) ~~Microbiological contaminants in accordance with OAR 333-007-0390 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.~~¶¶

(d) Mycotoxins in accordance with OAR 333-007-0425.¶¶

(e) Microbiological contaminants in accordance with OAR 333-007-0390.¶¶

(3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:¶¶

~~(a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and either:~~¶¶

~~(b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or~~¶¶

~~(c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.~~¶¶

(4) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the ~~Commission~~ Oregon Liquor and Cannabis Commission (Commission) under ORS 475C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶¶

(5) A process lot of a cannabinoid concentrate that is made only using food grade animal fat or food grade plant-based oil is not required to be tested for pesticides, heavy metals ~~starting March 1, 2023~~, ~~mycotoxins starting July 1, 2022~~, ~~mycotoxins~~, or microbiological contaminants ~~starting March 1, 2023~~ if:¶¶

(a) All marijuana or usable marijuana used to make the concentrate was tested for and passed:¶¶

(A) Pesticide testing in accordance with OAR 333-007-0400.¶¶

(B) Heavy metal testing in accordance with OAR 333-007-0415 ~~on or after March 1, 2023.~~¶¶

(C) Mycotoxin testing in accordance with OAR 333-007-0425 ~~on or after July 1, 2022.~~¶¶

(D) Microbiological contaminants in accordance with OAR 333-007-0390 ~~on or after March 1, 2023.~~¶¶

(b) The concentrate itself is only used to make a cannabinoid product intended for human consumption or use but not intended for inhalation and the concentrate is not sold directly to consumers or patients.¶¶

(6) Marijuana producers producing kief as permitted under OAR 845-025-2020:¶¶

(a) Must test every process lot for use by a consumer or patient prior to selling or transferring the kief for the following:¶¶

(A) Pesticides in accordance with OAR 333-007-0400.¶  
(B) ~~Water activity in accordance with OAR 333-007-0420 for kief manufactured before March 1, 2023.¶~~  
(C) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.¶  
(~~DC~~) Heavy metals in accordance with OAR 333-007-0415 if the kief is or was manufactured on or after March 1, 2023.¶  
(~~ED~~) Mycotoxins in accordance with OAR 333-007-0425 if the kief is or was manufactured on or after July 1, 2022.¶  
(~~FE~~) Microbiological contaminants in accordance with OAR 333-007-0390 if the kief is or was manufactured on or after March 1, 2023.¶  
(b) Must test every process lot intended for use by a processor in making a cannabinoid product, other than a finished inhalable cannabinoid product, for the following:¶  
(A) Pesticides in accordance with OAR 333-007-0400.¶  
(B) ~~Water activity in accordance with OAR 333-007-0420 for kief manufactured before March 1, 2023.¶~~  
(C) ~~Heavy metals in accordance with OAR 333-007-0415 if the kief is or was manufactured on or after March 1, 2023.~~Heavy metals in accordance with OAR 333-007-0415.¶  
(~~DC~~) Mycotoxins in accordance with OAR 333-007-0425 if the kief is or was manufactured on or after July 1, 2022.¶  
(~~ED~~) Microbiological contaminants in accordance with OAR 333-007-0390 if the kief is or was manufactured on or after March 1, 2023.  
Statutory/Other Authority: ORS 475C.544  
Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0341

RULE SUMMARY: OAR 333-007-0341: Amends rule to remove language tied to a past date.

CHANGES TO RULE:

333-007-0341

Compliance Testing Requirements for Finished Inhalable Cannabinoid Products

(1) A processor or processing site must test every process lot of a finished inhalable ~~C~~cannabinoid product prior to selling or transferring the product for the following:¶

(a) Pesticides in accordance with OAR 333-007-0400.¶

(b) Solvents in accordance with OAR 333-007-0410.¶

(c) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.¶

(d) Heavy metals in accordance with OAR 333-007-0415 ~~if the finished inhalable cannabinoid product is or was manufactured on or after March 1, 2023.~~¶

~~(e) Mycotoxins in accordance with OAR 333-007-0425 finished inhalable cannabinoid product is or was manufactured on or after July 1, 2022.~~¶

~~(f) Microbiological contaminants in accordance with OAR 333-007-0390 finished inhalable cannabinoid product is or was manufactured on or after March 1, 2023.~~¶

(e) Mycotoxins in accordance with OAR 333-007-0425.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390.¶

(2) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of finished inhalable ~~C~~cannabinoid products to a wholesaler licensed by the ~~Commission~~Oregon Liquor and Cannabis Commission (Commission) under ORS 475C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶

(3) To the extent that the testing required under this rule is also required under OAR 333-007-0340, a processor or processing site is only required to comply with the testing under this rule.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0342

RULE SUMMARY: OAR 333-007-0342: Amends rule to remove language tied to a past date.

CHANGES TO RULE:

333-007-0342

Compliance Testing Requirements for Industrial Hemp-Derived Vapor Items

(1) Every process lot of an industrial hemp-derived vapor item for use by a consumer or patient prior to selling or transferring the item must be tested for the following:¶

(a) Pesticides in accordance with OAR 333-007-0400.¶

(b) Solvents in accordance with OAR 333-007-0410.¶

(c) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.¶

(d) Heavy metals in accordance with OAR 333-007-0415 ~~if the industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023.~~¶

~~(e) Mycotoxins in accordance with OAR 333-007-0425 if the industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022.~~¶

~~(f) Microbiological contaminants in accordance with OAR 333-007-0390 if the industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023.~~¶

(e) Mycotoxins in accordance with OAR 333-007-0425.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390.¶

(2) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of industrial hemp-derived vapor items that the processor manufactured to a wholesaler licensed by the ~~Commission~~ Oregon Liquor and Cannabis Commission (Commission) under ORS 475C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE SUMMARY: OAR 333-007-0350: Amends rule to remove language tied to a past date. Amends rule language to change shall to must.

CHANGES TO RULE:

333-007-0350

Batch Requirements for Compliance Testing ¶¶

(1) Marijuana or usable marijuana. ¶¶

~~(a) A producer or grower must separate each harvest lot of marijuana or usable marijuana harvested before July 1, 2022, into no larger than 15-pound batches. ¶¶~~

~~(b) A producer or grower must separate each harvest lot of marijuana or usable marijuana harvested on or after July 1, 2022, into no larger than 50.0-pound batches. ¶¶~~

(2) Cannabinoid concentrates and extracts. ¶¶

(a) A process lot of a cannabinoid concentrate or extract is considered a batch. ¶¶

(b) A batch of a cannabinoid concentrate or extract must be produced using a standard operating procedure and result in one finished cannabinoid concentrate or extract that is uniform in texture and form. ¶¶

(3) Cannabinoid products. ¶¶

(a) A processor or processing site must separate process lots into not larger than 35,000 unit of sale batches. ¶¶

(b) A batch of a cannabinoid product must be produced using a standard operating procedure and result in a finished cannabinoid product that is uniform in potency, texture, and weight. A standard operating procedure may use different flavors or colors in a batch if the different flavors or colors: ¶¶

(A) Are substituted for one another at a 1:1 ratio; and ¶¶

(B) Do not affect the potency, texture, or weight of the finished cannabinoid product. ¶¶

(c) If a cannabinoid product is or may be sold in different quantities in a unit of sale, then the process lot ~~shall~~must be sampled based on the smallest unit of sale for the purposes of sampling and testing. All proposed units of sales must meet the Commission's concentration limit rules found in chapter 845, division 26. ¶¶

(4) Industrial hemp-derived vapor items. ¶¶

(a) A process lot of an industrial hemp-derived vapor item is considered a batch. ¶¶

(b) A batch of an industrial hemp-derived vapor item must be made from a standard operating procedure and result in one final industrial hemp-derived vapor item that is uniform in flavor, texture, and form. ¶¶

(5) Finished inhalable cannabinoid products. ¶¶

(a) A process lot of a finished inhalable cannabinoid product is considered a batch. ¶¶

(b) A batch of a finished inhalable cannabinoid product must be made from a standard operating procedure and result in one finished inhalable cannabinoid product that is uniform in flavor, texture, and form. ¶¶

(6) A grower and processing site must assign each batch a unique batch number and that unique batch number must be: ¶¶

(a) Documented and maintained in the grower and processing site records for at least two years and available to the Oregon Health Authority upon request; ¶¶

(b) Provided to the individual responsible for taking samples; and ¶¶

(c) Included on the batch label as required in OAR 333-007-0380. ¶¶

(7) A grower and processing site may not reuse a unique batch number. ¶¶

(8) For the purposes of this rule, "flavor" means: ¶¶

(a) The essential oil or essence which contains the flavoring constituents derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material. ¶¶

(b) Any substance, the function of which is to impart flavor, which is not derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material. ¶¶

(c) Flavor does not include flavoring constituents derived from the cannabis plant.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE SUMMARY: OAR 333-007-0360: Amends rule to remove language tied to a past date. Removing reference to OAR 333-007-0440 as that rule does not exist anymore. Adding clarification to the rule language to state a sufficient sample size must be taken for analysis for all requested tests including any potential reanalysis test that may also be requested. Amends rule language to change shall to must.

CHANGES TO RULE:

333-007-0360

Sampling and Sample Size Requirements for Compliance Testing ¶¶

(1) Marijuana or usable marijuana.¶¶

(a) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a processor or processing site to make a cannabinoid concentrate or extract.¶¶

(b) Sample increments taken must in total represent a minimum of 0.50 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in OAR 333-064-0100(2).¶¶

(c) A portion of homogenized samples taken from multiple batches of usable marijuana from the same harvest lot as described in OAR 333-064-0100(2)(f) may be combined into one sample for purposes of testing for adult use cannabinoids and CBD if the batches are the same strain and appear to be substantially similar in appearance and quality, regardless of the size of the multiple batches. Sampling must be performed in accordance with ORELAP-SOP-001 Rev 4.0 and on or after July 1, 2022, ORELAP-SOP-001 Revision 4.1.¶¶

(d) The whole batch of marijuana or usable marijuana must be made available for sampling and placed in containers that holds no more than 15.0 pounds of marijuana or usable marijuana.¶¶

(2) Cannabinoid concentrates, extracts, products, and finished inhalable cannabinoid products.¶¶

(a) The whole batch of finished cannabinoid concentrates, extracts, products, or finished inhalable cannabinoid products must be available for sampling.¶¶

(b) Samples of cannabinoid concentrates, extracts, products, and finished inhalable cannabinoid products intended for human consumption, use or ingestion for use by a consumer or patient must be taken from the finished cannabinoid concentrate, extract, product, or finished inhalable cannabinoid product as those terms are defined in OAR 333-007-0310, except for as outlined in subsection (2)(f) of this rule.¶¶

(c) For a cannabinoid concentrate, extract or finished inhalable cannabinoid product, the minimum number of sample increments that must be taken are established in Exhibit B, Table 7, incorporated by reference. The sample increments ~~shall~~must be combined as described in Exhibit B, Table 7, OAR 333-064-0100, and ORELAP-SOP-002 Revision 4.3. The primary sample, the duplicate sample and any required replicate samples must be prepared and analyzed separately.¶¶

(d) For a cannabinoid product, a minimum of one unit of sale chosen at random, is required for the primary sample and one unit of sale chosen at random, is required for the duplicate sample for testing in accordance with ~~OAR 333-007-0440~~, OAR 333-064-0100(2), and ORELAP-SOP-002 Revision 4.3. The primary sample and the duplicate sample must be prepared and analyzed separately.¶¶

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

(f) If baking of a cannabinoid edible is the final step to create a finished cannabinoid product, the processor or processing site may leave the production batch unbaked and only bake the samples chosen by the testing laboratory for sampling. Prior to sampling, the processor or processing site must ensure that the entire batch is available to the laboratory and in a form where the only remaining step to complete the edible is baking. If anything is added to the edible after baking, the entire batch must be baked and finished prior to sampling. Baking means to subject the item to dry heat, typically by an oven.¶¶

(3) Industrial hemp-derived vapor items.¶¶

(a) The whole finished batch of industrial hemp-derived vapor items must be available for sampling.¶¶

(b) Samples of industrial hemp-derived vapor items must be taken in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.¶¶

(c) The minimum number of sample increments that must be taken are established in Exhibit B, Table 7, incorporated by reference. The sample increments ~~shall~~must be combined into a primary sample and a duplicate sample as described in OAR 333-064-0100, ORELAP-SOP-002 Revision 4.3. The primary sample, the duplicate sample and any required replicate sample must be prepared and analyzed separately.¶¶

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

(4) Sufficient sample increments must be taken for analysis of all required tests, potential reanalysis tests, and the quality control performed by the testing laboratory for these tests.¶¶

NOTE: ORELAP SOPs are available under OAR 333-064-0100

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-007-0360.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340253>

AMEND: 333-007-0400

RULE SUMMARY: OAR 333-007-0400: Amends rule to clarify that a marijuana item fails testing when the presence of a pesticide is detected at or above the action limit in any sample, including any duplicate or replicate samples. Also, clarifying that any trailing zero to the right of the decimal point for a pesticide action limit is considered a significant figure. Adding a zero to the right of all action limits listed in Exhibit A, Table 3.

CHANGES TO RULE:

333-007-0400

Standards for Pesticides Compliance Testing ¶

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for pesticides must be tested by a laboratory for all the analytes listed in Exhibit A, Table 3, incorporated by reference.¶

(2) A batch fails pesticide testing if a laboratory detects the presence of a pesticide at or above the action levels listed in Exhibit A, Table 3 in any sample, including any duplicate or replicate samples.¶

(a) During an initial test where no reanalysis is requested; or¶

(b) Upon reanalysis as described in OAR 333-007-0450(1).¶

(3) The Oregon Health Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.¶

(4) Any trailing zero to the right of the decimal point for a pesticide listed in Exhibit A, Table 3 is considered a significant figure.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-007-0400.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340255>

AMEND: 333-007-0410

RULE SUMMARY: OAR 333-007-0410 Amends rule to clarify that a marijuana item fails testing when the presence of a solvent is detected at or above the action limit in any sample, including any duplicate or replicate samples. Also, clarifying that any trailing zero to the right of the decimal point for a solvent action limit is considered a significant figure. Adding a zero to the right of all action limits listed in Exhibit A, Table 4.

CHANGES TO RULE:

333-007-0410

Standards for Solvents Compliance Testing ¶¶

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for solvents must be tested by a laboratory for all the analytes listed in Exhibit A, Table 4 incorporated by reference.¶¶

(2) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):¶¶

(a) Detects the presence of a solvent at or above the action level listed in Exhibit A, Table 4 in any sample;¶¶

~~(b) Calculates a, including any duplicate or replicate samples;¶¶~~

~~(b) Calculates a relative percent difference (RPD) of more than 10.0 percent between the primary result and the duplicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4; or¶¶~~

(c) Calculates a relative standard deviation (RSD) of more than 10.0 percent between the primary result, the duplicate result and any replicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4.¶¶

(3) The Oregon Health Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years.¶¶

(4) Any trailing zero to the right of the decimal point for a solvent listed in Exhibit A, Table 4 is considered a significant figure.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-007-0410.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340257>

AMEND: 333-007-0415

RULE SUMMARY: OAR 333-007-0415: Amends rule to clarify that a marijuana item fails testing when the presence of a heavy metal is detected at or above the action limit in any sample, including any duplicate or replicate samples. Also, clarifying that any trailing zero to the right of the decimal point for a heavy metal action limit is considered a significant figure. Adding a zero to the right of all action limits listed in Exhibit A, Table 8.

CHANGES TO RULE:

333-007-0415

Standards for Heavy Metal Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for heavy metals must be tested by a laboratory for the analytes listed in Exhibit A, Table 8 incorporated by reference.¶¶

(2) A batch fails heavy metal testing if a laboratory detects the presence of a heavy metal at or above the action levels listed in Exhibit A, Table 8 in any sample, including any duplicate or replicate samples.¶¶

(a) During an initial test where no reanalysis is requested; or¶¶

(b) Upon reanalysis as described in OAR 333-007-0450(1).¶¶

(3) Any trailing zero to the right of the decimal point for a heavy metal listed in Exhibit A, Table 8 is considered a significant figure.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-007-0415.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340259>

AMEND: 333-007-0420

RULE SUMMARY: OAR 333-007-0420: Amends rule language to remove reference to dates that have passed. Also, clarifying that any trailing zero to the right of the decimal point for a water activity and moisture content action limit is considered a significant figure. Adding a zero to the right of all action limits listed.

CHANGES TO RULE:

333-007-0420

Standards for Testing Water Activity and Moisture Content ¶

(1) Usable marijuana must be tested by a laboratory for:¶

(a) Water activity; and¶

(b) Moisture content.¶

~~(2) Kief manufactured before March 1, 2023, must be tested by a laboratory for water activity unless the marijuana or usable marijuana used to produce the kief has already passed testing for water activity prior to producing the kief in accordance with OAR 333-007-0320(6).~~(6) If a sample has a water activity rate of more than 0.650 Aw the sample fails.¶

~~(3) If a sample has a water activity rate~~moisture content of more than ~~0.65 Aw~~15.0 percent the sample fails.¶

~~(4) If a sample has a moisture content of more than 15 percent the sample fails~~Any trailing zero to the right of the decimal point listed under this rule is considered a significant figure.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0425

RULE SUMMARY: OAR 333-007-0425: Amends rule to clarify that a marijuana item fails testing when the presence of a mycotoxin is detected at or above the action limit in any sample, including any duplicate or replicate samples. Also, clarifying that any trailing zero to the right of the decimal point for a mycotoxin action limit is considered a significant figure. Adding a zero to the right of all action limits listed in Exhibit A, Table 9.

CHANGES TO RULE:

333-007-0425

Standards for Mycotoxin Contaminants Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for mycotoxin must be tested by a laboratory for:

(a) Aflatoxins B1, B2, G1, G2; and

(b) Ochratoxin A.

(2) A batch fails mycotoxin testing if, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1), the laboratory detects ~~levels~~ the presence of any mycotoxin at or above the action levels listed in Exhibit A, Table 9 in any sample, including any duplicate or replicate samples.

(3) Any trailing zero to the right of the decimal point for a mycotoxin listed in Exhibit A, Table 9 is considered a significant figure.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-007-0425.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340261>

RULE SUMMARY: OAR 333-007-0430: Amends rule to clarify that a process lot of a marijuana item fails potency testing if any sample increment exceeds the maximum concentration limit permitted in a package by the Oregon Liquor and Cannabis Commission's concentration limit rules in OAR chapter 845, division 26. Adding a significant zero to percents or quantities that are listed under this rule. Adding new criteria for when a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails for total CBD based on exceeding the relative percent difference or relative standard deviation. Adding new language around target potency criteria for a cannabinoid product, that an investigation must occur if the target is not met and when reanalysis may occur.

CHANGES TO RULE:

333-007-0430

Standards for Adult Use Cannabinoid and CBD Compliance Testing ¶¶

(1) A laboratory must test for all of the following analytes when testing a marijuana item or industrial hemp-derived vapor item for potency:¶¶

- (a) Delta-9-THC.¶¶
- (b) Delta-9-THCA.¶¶
- (c) Delta-8-THC.¶¶
- (d) CBD.¶¶
- (e) CBDA.¶¶

(2) A process lot of a cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):¶¶

(a) The amount of delta-8-THC, total delta-9-THC or total CBD, as calculated pursuant to OAR 333-064-0100, between the primary sample and the duplicate sample exceeds 10.0 percent relative percent difference (RPD) or between the primary sample, duplicate sample and any replicate samples exceeds 10.0 percent relative standard deviation (RSD); or¶¶

(b) The amount or percentage of delta-8-THC, total delta-9-THC, as calculated pursuant to OAR 333-064-0100, for any sample increment exceeds the maximum concentration limits permitted in a package by ~~over 10 percent as specified in~~ the Oregon Liquor and Cannabis Commission's concentration limit rules in OAR chapter 845, division 26, as applicable.¶¶

(3) Notwithstanding subsection (2)(a) of this rule:¶¶

(a) A cannabinoid product that has less than 5.0 mg of total delta-9-THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶¶

(b) A cannabinoid product that has less than 10.0 mg of total CBD per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶¶

(c) A cannabinoid product that has less than 5.0 mg of delta-8-THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶¶

(d) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 5.0 mg total delta-9-THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶¶

(e) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 10.0 mg total CBD per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.¶¶

(f) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has ~~less than 5 mg delta-8-THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule~~ at least 10.0 mg of total CBD per gram and less than 50.0 mg of total CBD per gram as calculated and reported pursuant to OAR 333-064-0100 fails potency testing if the primary sample and the duplicate sample exceeds 50.0 percent RPD or between the primary sample, duplicate sample and any replicate samples exceeds 50.0 percent RSD.¶¶

(g) A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 5.0 mg delta-8-THC per gram as calculated pursuant to OAR 333-064-0100 does not fail

potency testing based on exceedance of the RPD or RSD as described in subsection (2)(a) of this rule.<sup>¶</sup>

(4) If a registrant or licensee provided the testing laboratory with a target potency in accordance with OAR 333-007-0315(8), and a process lot of a cannabinoid product does not meet its target potency within 10.0 percent of the value calculated as described in OAR 333-064-0100(4), but the lot otherwise meets the requirements of subsection (2) of this rule, the registrant or licensee may request reanalysis in accordance with OAR 333-007-0450(10)(c). Prior to requesting reanalysis, the registrant or licensee must conduct an investigation to determine the cause of not meeting the target potency. The investigation must be documented in writing, include any corrective action taken if applicable, and made available for review upon request by the Oregon Health Authority or the Oregon Liquor and Cannabis Commission.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE SUMMARY: OAR 333-007-0450: Amends rule language to remove reference to dates that have passed. Adds reference to each specific contaminant testing rule sections when an item must be tested again. Added language to allow for a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that fails for total CBD based on exceeding the relative percent difference or relative standard deviation to be remediated by re-mixing to meet the standard. Added a section on how a cannabinoid product is to be re-analyzed and re-tested for potency and which potency result should be considered the final result.

CHANGES TO RULE:

333-007-0450

Failed Test Samples ¶¶

- (1) If a sample or a duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must re-sample the batch and confirm that result in order for the batch to pass testing.¶¶
- (a) If a registrant or licensee requests to have a sample reanalyzed, the registrant or licensee must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the registrant or licensee. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.¶¶
- (b) If a registrant or licensee has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the registrant or licensee has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory re-sample the batch and confirm the passed test result. The re-testing must be completed by the second laboratory within 30 days from the date the re-testing was requested. The second laboratory performing the re-testing:¶¶
- (A) May not be performed at a laboratory under the same ownership as the original laboratory that performed the testing.¶¶
- (B) May not be done by a laboratory that was subcontracted to do the original testing.¶¶
- (C) May only conduct re-testing for the compliance test that initially failed.¶¶
- (c) If reanalysis in accordance with subsection (1)(a) or re-testing in accordance with subsection (1)(b) is ordered, then the batch must remain in its original quantity as it was initially submitted to the laboratory for testing and may not be subdivided.¶¶
- (d) A registrant must inform the Oregon Health Authority (Authority) immediately, of the following, in a manner prescribed by the Authority:¶¶
- (A) A request for reanalysis of a sample;¶¶
- (B) The testing results of the reanalysis;¶¶
- (C) A request for re-testing; and¶¶
- (D) The results of re-testing.¶¶
- (2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:¶¶
- (a) May be remediated or sterilized in accordance with this rule.¶¶
- (b) Must be destroyed in a manner specified by the Authority or the Oregon Liquor and Cannabis Commission (Commission) if it is not or cannot be remediated or sterilized under this rule.¶¶
- (c) May not be combined with other batches as part of remediation or further processing.¶¶
- (3) If a registrant is permitted to remediate or sterilize under this rule, the registrant must provide notice to the Authority of the registrant's intent to remediate or sterilize.¶¶
- (4) Except as otherwise permitted under this rule, a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that is permitted to undergo remediation cannot be further processed into a cannabinoid product during the remediation process.¶¶
- (5) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.¶¶
- (6) Failed microbiological contaminant testing.¶¶
- (a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing the batch may either:¶¶
- (A) Be remediated using a sterilization process; or¶¶
- (B) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO2 closed loop system.¶¶

(b) If a sample from a batch of a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails microbiological contaminant testing the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon-based solvent or a CO2 closed loop system.¶¶

(c) A batch that is remediated through a sterilization process in accordance with subsection (a) or (b) of this section must be sampled in accordance with OAR 333-007-0360 and must be tested for:¶¶

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

(B) Solvents if required per OAR 333-007-0410;¶¶

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

(D) Water activity and moisture content if required per OAR 333-007-0420;¶¶

(E) Potency in accordance with OAR 333-007-0430(4);¶¶

(F) Heavy metals ~~if the marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after March 1, 2023; and~~¶¶

~~(G) Mycotoxins if the marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after July 1, 2022;~~ in accordance with OAR 333-007-0415; and¶¶

(G) Mycotoxins in accordance with OAR 333-007-0425.¶¶

(d) A batch that fails microbiological contaminant testing after undergoing remediation through a sterilization process in accordance with paragraph (a)(A) of this section must be destroyed in a manner specified by the Authority or the Commission, or may be further processed as described in paragraph (a)(B) of this section.¶¶

(7) Failed solvent testing.¶¶

(a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.¶¶

(b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled in accordance with OAR 333-007-0360 and must be re-tested for:¶¶

(A) Solvents;¶¶

~~(B) Pesticides in accordance with OAR 333-007-0410;~~¶¶

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

(C) Potency in accordance with OAR 333-007-0430(4);¶¶

(D) Heavy metals ~~if the marijuana item or industrial hemp-derived vapor item was manufactured on or after March 1, 2023;~~¶¶

~~(E) Mycotoxins if the marijuana item or industrial hemp-derived vapor item was manufactured on or after July 1, 2022; and~~¶¶

~~(F) Microbiological contaminants if the marijuana item or industrial hemp-derived vapor item was manufactured on and after March 1, 2023;~~ in accordance with OAR 333-007-0415;¶¶

(E) Mycotoxins in accordance with OAR 333-007-0425; and¶¶

(F) Microbiological contaminants in accordance with OAR 333-007-0390.¶¶

(c) A batch that fails solvent testing that is not remediated must be destroyed in a manner specified by the Authority or the Commission.¶¶

(8) Failed water activity or moisture content testing.¶¶

(a) If a sample from a batch of marijuana or usable marijuana fails for water activity or moisture content the batch from which the sample was taken may:¶¶

(A) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch; or¶¶

(B) Continue to dry or cure.¶¶

(b) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be re-sampled in accordance with OAR 333-007-0360 and re-tested for:¶¶

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

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

(C) Potency in accordance with OAR 333-007-0430(4);¶¶

(D) Heavy metals ~~if the marijuana or usable marijuana was harvested on or after March 1, 2023;~~¶¶

~~(E) Mycotoxins if the marijuana or usable marijuana was harvested on or after July 1, 2022;~~ in accordance with OAR 333-007-0415;¶¶

(E) Mycotoxins in accordance with OAR 333-007-0425; and¶¶

~~(F) Microbiological contaminants if the marijuana or usable marijuana was harvested on and after March 1, 2023;~~ in accordance with OAR 333-007-0390.¶¶

(9) Failed pesticide testing.¶¶

(a) If a sample from a batch of marijuana or usable marijuana fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority or the Commission, except as permitted under subsection (c) of this section. A batch may not be destroyed without obtaining permission from the Authority or the

Commission.¶¶

(b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample of usable marijuana failed a pesticide test.¶¶

(c) If a sample from a batch of marijuana or usable marijuana fails pesticide testing but only for the analytes piperonyl butoxide or pyrethrins, and the Oregon Department of Agriculture determines that the products used were listed on the Department's Guide List for Pesticides and Cannabis and the product was applied in accordance with the label, the Authority or the Commission may permit the producer or grower to remediate the usable marijuana using procedures that would reduce the concentration of pesticides to less than the action level. A batch of usable marijuana that is permitted to be remediated must be re-sampled in accordance with OAR 333-007-0360 and re-tested for:¶¶

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

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

(C) Potency in accordance with OAR 333-007-0430~~(1);~~¶¶

(D) Microbiological contaminants ~~if the marijuana item was harvested on or after March 1, 2023;~~¶¶

~~(E) Heavy metals if the marijuana item was harvested on or after March 1, 2023;~~ in accordance with OAR 333-007-0390;¶¶

(E) Heavy metals in accordance with OAR 333-007-0415; and¶¶

~~(F) Mycotoxins if the marijuana item was harvested on or after July 1, 2022;~~ in accordance with OAR 333-007-0425.¶¶

(d) If a processor or a processing site is only processing with marijuana or usable marijuana that has passed pesticide testing in accordance with OAR 333-007-0400 and a sample from a batch of a cannabinoid concentrate or extract fails pesticide testing the batch may be remediated using procedures that would reduce the concentration of pesticides to less than the action level.¶¶

(e) If a batch of industrial hemp-derived vapor item fails pesticides testing, it may only be remediated using procedures that would reduce the concentration of pesticides to less than the action level if the input material used to make the industrial hemp-derived vapor item passed pesticide testing in accordance with OAR 333-007-0400.¶¶

(f) A batch that is remediated in accordance with subsection (d) or (e) of this section must be re-sampled in accordance with OAR 333-007-0360 and re-tested for:¶¶

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

(B) Potency in accordance with OAR 333-007-0430~~(1);~~¶¶

(C) Solvent testing if required per OAR 333-007-0410;¶¶

(D) Heavy metals;¶¶

~~(E) Mycotoxins in accordance with OAR 333-007-0415;~~¶¶

(E) Mycotoxins in accordance with OAR 333-007-0425; and¶¶

(F) Microbiological contaminants in accordance with OAR 333-007-0390.¶¶

(g) If a sample from a batch of finished inhalable cannabinoid products fails pesticide testing, the batch may not be remediated and must be destroyed in a manner specified by the Authority or the Commission.¶¶

(h) A batch that is remediated but after being re-sampled and re-tested fails pesticide testing must be destroyed as ordered by the Authority or the Commission.¶¶

(10) Failed potency testing.¶¶

(a) A marijuana item or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-0430(2)(b) may be repackaged in a manner that enables the item to meet the concentration limit standards in the Commission's concentration limit rules in OAR chapter 845, division 26, as applicable. A marijuana item or industrial hemp-derived vapor item that is repackaged in accordance with this subsection must be re-sampled and re-tested in accordance with these rules.¶¶

(b) A marijuana item or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-0430(2)(a) or OAR 333-007-0430(3)(f) may be re-mixed to meet the standards in OAR 333-007-0430(2)(a) or OAR 333-007-0430(3)(f). A marijuana item or industrial hemp-derived vapor item that is re-mixed must be re-sampled in accordance with OAR 333-007-0360 and re-tested in accordance with these rules for the marijuana item or industrial hemp-derived vapor item for:¶¶

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

(B) Potency in accordance with OAR 333-007-0430~~(1);~~¶¶

(C) Solvent testing if required per OAR 333-007-0410;¶¶

~~(D) Heavy metals if the marijuana item or industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023;~~ in accordance with OAR 333-007-0415;¶¶

(E) Mycotoxins in accordance with OAR 333-007-0425; and¶¶

(F) Microbiological contaminants in accordance with OAR 333-007-0390.¶¶

(c) A cannabinoid product that fails potency testing under OAR 333-007-0430(4) may be reanalyzed in accordance with subsection (1) of this rule for potency in accordance with OAR 333-007-0430.¶¶

~~(E) Mycotoxins if the marijuana item or industrial hemp-derived vapor item is or was manufactured on~~  
~~reanalyzed potency test result is outside the parameters of the target potency as described in OAR 333-007-~~  
~~0430(4), the reanalyzed test result will be considered the amount of~~ after July 1, 2022; and

~~(F) Microbiological contaminants if~~ adult use cannabinoids in the cannabinoid product.

If the reanalyzed potency test result is within the ~~marijuana item or industrial hemp-derived vapor item is or was~~  
~~manufactured on and after March 1, 2023,~~ get potency as described in OAR 333-007-0430(4), the registrant or  
licensee must request re-testing in accordance with subsection (1) of this rule for potency in accordance with OAR  
333-007-0430. The potency result from the re-test will be considered the amount of adult use cannabinoids in the  
item.

(11) Failed heavy metal testing.

(a) If a sample from a batch of marijuana or usable marijuana fails heavy metal testing, the batch may be remediated  
by processing into a cannabinoid concentrate or extract if the processing method reduces the concentration of  
heavy metals to less than the action levels.

(b) If a sample from a cannabinoid concentrate or extract fails heavy metal testing, the batch may be remediated  
using procedures that would reduce the concentration of heavy metals to less than the action level.

(c) If a sample from a batch of finished inhalable cannabinoid product or industrial hemp-derived vapor item fails  
for heavy metals, the batch may not be remediated and must be destroyed in a manner specified by the Authority  
or Commission.

(d) A batch that is remediated in accordance with subsection (a) or (b) of this section must be re-sampled in  
accordance with OAR 333-007-0360 and re-tested for:

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

(B) Solvents if required under OAR 333-007-0410;

(C) Potency in accordance with OAR 333-007-0430(4);

(D) Heavy metals;

~~(E) Mycotoxins in accordance with OAR 333-007-0415;~~

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

(F) Microbiological contaminants in accordance with OAR 333-007-0390.

(e) A batch that fails heavy metal testing that is not remediated must be destroyed in a manner specified by the  
Authority, Commission, or the Department of Agriculture.

(12) Failed mycotoxin testing. If a sample from a batch of a marijuana item or industrial hemp-derived vapor item  
fails mycotoxin testing the batch may not be remediated and must be destroyed in a manner specified by the  
Authority, Commission, or the Department of Agriculture.

(13) A registrant must inform a laboratory prior to samples being taken that the batch has failed a test and is being  
re-tested after undergoing remediation or sterilization.

(14) A registrant must, as applicable:

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing  
the concentration of solvents.

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under  
these rules.

(15) If a batch fails a test under these rules a registrant:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and  
the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0600

RULE SUMMARY: OAR 333-007-0600: Clarifies rule language regarding when the Oregon Health Authority may request reanalysis by the cannabis reference laboratory.

CHANGES TO RULE:

333-007-0600

Cannabis Reference Laboratory

(1) The Oregon Health Authority (Authority) may request that the cannabis reference laboratory conduct any of the following:¶

(a) Audit testing as described in OAR 333-007-0480; or¶

(b) Testing if the Authority has reason to believe the marijuana item, industrial hemp or hemp item is not in compliance with ORS 475C.544 or these rules.¶

(2) The Authority may consider a test conducted by the cannabis reference laboratory to be a compliance test.¶

(3) If a test conducted by the cannabis reference laboratory indicates a sample fails to comply with concentration limits in OAR chapter 845, division 26 or an action level in OAR chapter 333, division 7, the Authority may invalidate the results of the test conducted by the original laboratory. If the Authority invalidates a compliance test result:¶

(a) The Authority must notify the registrant who ordered the compliance test.¶

(b) The registrant must follow the applicable procedures under OAR 333-007-0450 regarding failed test samples.¶

(c) ~~Subject to any reanalysis~~ The Authority may request reanalysis by the reference laboratory conducted pursuant to OAR 333-007-0450, ~~+~~¶

(d) ~~The Authority may request or~~ require the recall of any marijuana items, industrial hemp or hemp items associated with a failed sample that have been sold or transferred. The recall must be conducted in accordance with instructions provided by the Authority. The registrant must either:¶

(A) Destroy the affected marijuana items, industrial hemp, or hemp items; or¶

(B) Remediate the affected marijuana items, industrial hemp, or hemp items in accordance with OAR 333-007-0450.¶

(4) The Authority may request or require a recall based on the cannabis reference laboratory audit testing.

Statutory/Other Authority: ORS 475C.523

Statutes/Other Implemented: ORS 475C.523

RULE SUMMARY: OAR 333-064-0025: Amends rule to clarify the definition of batch for cannabis sampling. Amends rule to add a new definition for "target potency", "ISO / IEC", and "ISO / IEC 17043". Amends the definition of "Proficiency Testing (PT)" for cannabis and psilocybin fields of accreditation (FOA) to allow ORELAP approved "ISO / IEC 17043" PT providers. Amends the definition of "homogenization". Amends the definition of "total potential psilocin" to "total psilocybin equivalent".

#### CHANGES TO RULE:

#### 333-064-0025 Definitions ¶¶

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

- (1) "Accrediting body" means the official accrediting authority for the Oregon Environmental Laboratory Accreditation Program comprised of the Administrator of the Oregon State Public Health Laboratory or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory Administrator of the Department of Agriculture or designee.¶¶
- (2) "Adult use cannabinoid" has the meaning given that term in OAR 333-007-0310.¶¶
- (3) "Air" as a matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.¶¶
- (4) "Artificially derived cannabinoid" has the meaning given that term in OAR 333-007-0310.¶¶
- (5) "Authority" means the Oregon Health Authority.¶¶
- (6) "Batch" means:¶¶
  - (a) For sample analysis, this term has the meaning assigned in the TNI Standard which is a group of samples that are prepared or analyzed together in the laboratory with the same process and personnel, using the same lot(s) of reagents.¶¶
  - (A) A preparation batch is composed of 1 to 20 environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing the first and last sample in the batch to be 24 hours.¶¶
  - (B) An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples.¶¶
- (b) For cannabis sampling:¶¶
  - ~~(A) A quantity of marijuana or usable marijuana from a harvest lot; or~~¶¶
  - ~~(B) A quantity of cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item from a process lot; this term has the same meaning given that term in OAR 333-007-0310.~~¶¶
- (c) For psilocybin sampling, this term has the same meaning given that term in OAR 333-333-1010.¶¶
- (7) "Biological tissue" as a matrix means samples of biological tissue, excluding those of human origin, and includes:¶¶
  - (a) Usable marijuana and hemp samples for compliance testing.¶¶
  - (b) Psilocybin-containing dried fungal tissue, such as fruiting bodies or hyphae.¶¶
- (8) "Cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶¶
- ~~(9)~~ "Cannabis" has the meaning given that term in OAR 333-007-0310.¶¶
- ~~(9-10)~~ "Cannabis sampling" means an activity related to obtaining a representative sample of a marijuana item or industrial hemp-derived vapor item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.¶¶
- ~~(10-1)~~ "Cannabis Tracking System" or "CTS" has the meaning given that term in OAR 333-007-0310.¶¶
- ~~(14-2)~~ "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.¶¶
- ~~(12-3)~~ "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-85-2.¶¶
- ~~(13-4)~~ "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 EPAUnited States Environmental Protection Agency (EPA) to promulgate air quality standards, monitor and enforce them.¶¶
- ~~(14-5)~~ "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.¶¶
- ~~(15-6)~~ "Commission" means the Oregon Liquor and Cannabis Commission.¶¶

- (167) "Delta-8-tetrahydrocannabinol" or "Delta-8 THC" means (6aR, 10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.¶
- (178) "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.¶
- (189) "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.¶
- (1920) "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.¶
- (201) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which the Oregon Environmental Laboratory Accreditation Program (ORELAP) offers accreditation.¶
- (242) "Finished cannabinoid concentrate or extract" has the meaning given that term in OAR 333-007-0310.¶
- (223) "Finished cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶
- (234) "Finished inhalable cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶
- (245) "Industrial hemp-derived vapor item" has the meaning given that term in OAR 333-007-0310.¶
- (256) "Homogenization" means physically manipulating a sample to make the sample's material uniform in composition and properties throughout, including but not limited to and reducing particle size to a fine uniform powder for material for biological tissue and solid materials or combining all layers or phases of a liquid or semi-solid sample into a uniform substance.¶
- (267) "ISO / IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrochemical Commission (IEC). ¶
- (28) "ISO / IEC 17043" means the general requirements established by the ISO / IEC for proficiency testing. Available at <https://www.iso.org/home.html>. ¶
- (29) "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.¶
- (2730) "Marijuana item" has the meaning given that term in OAR 333-007-0310.¶
- (2831) "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.¶
- (329) "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.¶
- (303) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.¶
- (344) "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.¶
- (325) "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.¶
- (336) "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.¶
- (347) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.¶
- (358) "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, proficiency testing (PT) results and on-site assessment results as described in the TNI Standards.¶
- (369) "Proficiency testing (PT)" means:¶

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

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

(c) The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.¶

~~(3740)~~ "Psilocin analyte" means 4-hydroxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-53-6.¶

~~(3841)~~ "Psilocybin analyte" means 4-phosphoryloxy-N,N-dimethyltryptamine, Chemical Abstracts Service Number 520-52-5.¶

~~(3942)~~ "Psilocybin product" has the meaning given that term in OAR 333-333-1010.¶

~~(403)~~ "Psilocybin Tracking System" or "PTS" has the meaning given that term in OAR 333-333-1010.¶

~~(444)~~ "Public water system" means a water system as defined in OAR 333-061-0010.¶

~~(425)~~ "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.¶

~~(436)~~ "Replicate sample" is a sample in addition to the primary and duplicate samples that consists of the same number of increments taken in the same manner as the primary and duplicate samples.¶

~~(447)~~ "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.¶

~~(458)~~ "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.¶

~~(469)~~ "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.¶

~~(4750)~~ "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.¶

~~(4851)~~ "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act, and includes:-¶

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

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

~~(4952)~~ "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.¶

~~(503)~~ "Total Potential target potency" has the meaning given that term in OAR 845-025-7000.¶

~~(54)~~ "Total Psilocybin equivalent" means the sum of the psilocybin analyte concentration and 0.71914 times the psilocybin analyte concentration. This number is the maximum theoretical concentration of psilocybin in the sample.¶

~~(545)~~ "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.¶

~~(526)~~ "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](http://www.nelac-institute.org)¶

~~(537)~~ "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0160.¶

~~(548)~~ "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.¶

~~(559)~~ "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.¶

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

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150, 448.280, 475C.544, 475C.560, 475A.590, 475A.606

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280, 475C.544, 475C.560, 475A.590, 475A.606

RULE SUMMARY: OAR 333-064-0100: Clarifies rule language to change “Rev” to “Revision” for sampling protocols. Clarifies rule language for which sampling regulations under OAR 333-007 apply to finished cannabinoid concentrate, extract, product, or industrial hemp-derived vapor products. Clarifies rule language from “Oregon Liquor and Cannabis Commission seed to sale” to “Cannabis Tracking System (CTS)”. Clarifies rule language around sufficient sample size for any potential reanalysis taken during sampling. Amends rule language around sample handling and homogenization including a requirement that the homogenization process for marijuana and usable marijuana must homogenize the sample as collected and make the entire sample uniform to less than or equal to 1 millimeter (mm) and the laboratories perform a validation study prior to using the homogenization process. Amends rule to clarify how laboratories may combine samples as permitted under OAR 333-007-0360(1)(c). Amends rule language to add requirements for laboratory control sample (LCS) characterization. Clarifies rule language that a laboratory must analyze usable marijuana samples as collected. Amends rule language in Exhibit C, Table 1 to add requirements for initial calibration verification (ICV) and continuing calibration verification (CCV) quality control requirements. Adds a zero to the right of all limits listed in Exhibit C, Table 1. Adds clarification of required limit of quantification (LOQ) for adult-use cannabinoids. Amends rule language to add list of prohibited activities during testing and that laboratories must train personnel on this during data integrity training. Amends rule to add clarifications on how to perform rounding of results. Amends rule language to change shall to must.

CHANGES TO RULE:

333-064-0100

Cannabis Sampling Procedures and Testing ¶¶

- (1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.¶¶
- (2) Sampling.¶¶
- (a) A laboratory must have and follow marijuana item and industrial hemp-derived vapor items sampling policies and procedures, accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP), that:¶¶
- (A) Ensure sampling will result in a sample that is representative of the batch being sampled.¶¶
- (B) Require sampling and laboratory personnel to document and collect any information necessary for compliance with these rules, OAR chapter 333, division 7, and any applicable TNI Standards.¶¶
- (C) Require chain of custody procedures consistent with TNI ~~EL Standard V4~~ Module 1 Module 2 5.7 and 5.8.¶¶
- (D) Are appropriate to the matrix being sampled.¶¶
- (E) Are consistent with OAR 333-007-0360 and 333-007-0370 and the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:¶¶
- (i) Usable Marijuana: ORELAP-SOP-001 Revision 4.1; and¶¶
- (ii) Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items: ORELAP-SOP-002 Revision 4.3.¶¶
- (F) Ensure that only the finished cannabinoid concentrate, extract, product, or industrial hemp-derived vapor item is sampled if testing on the finished cannabinoid concentrate, extract, product, or industrial hemp-derived vapor item is required under OAR 333-007-0330 ~~and~~, OAR 333-007-0340, or OAR 333-007-0341.¶¶
- (G) Contain training and education requirements for sampling personnel.¶¶
- (b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana or industrial hemp-derived vapor item samples being taken.¶¶
- (c) Laboratory personnel that perform sampling must:¶¶
- (A) Comply with the laboratory's accredited sampling policies and procedures.¶¶
- (B) After taking samples:¶¶
- (i) Document the samples in accordance with subsection (2)(e) of this rule; and¶¶
- (ii) If sampling for a licensee or a registrant required to comply with Cannabis Tracking System (CTS) tracking under ORS 475C.871, record the sampling and transfer information in the ~~Oregon Liquor and Cannabis Commission's (Commission's) seed to sale system~~ CTS, as required by the Oregon Health Authority (Authority) and the ~~Commission; and Oregon Liquor and Cannabis Commission (Commission)~~;¶¶
- (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; and¶¶
- (D) Take sample increments that are representative of the batch being sampled.¶¶
- (d) A sufficient sample size must be taken for analysis and potential reanalysis of all requested tests and the quality

control performed by the testing laboratory for these tests.¶¶

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

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

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

(C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI Standard requirements.¶¶

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.¶¶

(E) Place the laboratory identification code as a durable mark on each sample container.¶¶

(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.¶¶

(f) Combining sample increments.¶¶

(A) Sample increments collected from the same batch of usable marijuana ~~shall~~must be combined into a single sample by a laboratory prior to testing.¶¶

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

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

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

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

~~(C3)~~ Sample handling and homogenization.¶¶

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

(A) On and after March 1, 2027, the laboratory's homogenization process for marijuana or usable marijuana must make the entire sample uniform to less than or equal to 1 millimeter (mm). The laboratory must homogenize the sample as collected and may not remove or add plant material such as stems or leaves prior to the homogenization process. The laboratory must ensure the homogenized sample is mixed, and a representative portion of the homogenized sample is used for compliance tests. The laboratory must perform and document an initial validation to demonstrate the laboratory's homogenization process for marijuana or usable marijuana achieves a sample uniformity of equal to or less than 1 mm, where at least 99 percent of the sample achieves the particle size of 1 mm or less. The laboratory must perform a new initial validation if any changes are made to the homogenization process for marijuana or usable marijuana prior to using the new homogenization process on samples for compliance tests.¶¶

~~(iB)~~ 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.¶¶

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

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

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

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

~~(gA)~~ To combine a homogenized sample for testing as permitted by OAR 333-007-0360(1)(c), a proportionally representative amount of material must be withdrawn from each homogenized sample and then the withdrawn material from each sample must be combined to produce the combined sample.¶¶

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

(d) Sample replicate analysis for concentrates, extracts, finished inhalable cannabinoid products, and industrial

hemp-derived vapor items.¶

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

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

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

~~(34)~~ Compliance testing validity.¶

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

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

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

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

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

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

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

~~(C) must be within the limits specified in Exhibit C, Table 1.~~¶

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

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

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

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

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

~~(45)~~ 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:¶

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

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

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

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

~~(56)~~ Report delta-8 THC, total delta-9 THC, and total CBD for useable marijuana as dry weight. A laboratory must analyze the sample as collected and received and report delta-8 THC, total delta-9 THC and total CBD content by dry weight calculated as follows:¶

(a)  $P \text{ delta-8 THC(dry)} = P \text{ delta-8 THC(wet)} / [1 - (P \text{ moisture}/100)]$ ¶

¶

(b)  $P \text{ total delta-9 THC(dry)} = P \text{ total delta-9 THC(wet)} / [1 - (P \text{ moisture}/100)]$ ¶

¶

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

~~(67)~~ 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:¶

(A) Standard Deviation¶

$S = (((x_i - x)^2) / (n - 1))$ ¶

(B) Relative Standard Deviation¶

$\%RSD = (S/x) * 100$ ¶

(c) For purposes of this section:¶

(A) S = standard deviation.¶

(B) n = total number of values.¶

(C)  $x_i$  = 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~~may 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.¶

~~(78)~~ Tentative Identification of Unknown Compounds.¶

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

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

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

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

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

~~(89)~~ A laboratory must provide:¶

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

(b) A sample or a portion of a sample to the Department upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the ~~Commission's seed to sale tracking system~~TS.¶

~~(910)~~ A laboratory performing tests for a licensee or a registrant required to use CTS under ORS 475C.871 must enter any information required by the Commission or the Authority in CTS.¶

~~(101)~~ 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.¶

~~(142)~~ The Authority may, in its discretion, permit a laboratory to deviate from the TNI Standard in order to comply with OAR 333-007-0300 to 333-007-0600 and these rules based on the state's needs. Permission to deviate from the TNI Standard must be in writing from the Authority.¶

~~(123)~~ A laboratory must be able to demonstrate that its limit of quantitation (LOQ) for all matrices in compliance testing is:¶

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

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

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

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

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

(134) When performing calculations, a laboratory may not round any values during intermediate steps of a

calculation, except as described in subsection (a) of this section.

(a) A laboratory may only round intermediate values to six significant digits after the decimal point.

(b) Rounding may only occur after all calculation steps have been completed.

(15) A laboratory must have and implement a written policy identifying the following activities as prohibited. A laboratory must train personnel to this policy during the data integrity training required by the TNI Standard. A laboratory is prohibited from the following actions:

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

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

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

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

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

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

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

(h) Inappropriately preparing and analyzing quality control samples;

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

(j) Performing improper manual integrations;

(k) Concealing a known analytical or sample problem;

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

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

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

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

(p) Performing repeated testing or additional testing and reporting the mean results for any testing other than potency in usable marijuana, except as allowed for potency of primary, duplicate, and replicate samples in this subsection; and

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

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

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

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

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

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

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

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

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

(16) 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.

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

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 475C.544, 475C.560, 438.620

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 475C.544, 475C.560, 438.620

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-064-0100.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340271>

RULE SUMMARY: OAR 333-064-0110: Amends rule language to add items that are required on test reports, including clarifying statement of compliance, how to report averaged results of potency in marijuana or usable marijuana, relative percent difference (RPD), and relative standard deviation (RSD) of primary, duplicate, and replicate samples, significant figure requirements for test results and quality control results, quality control results in percent recovery, and identification of failed quality control results. Amends rule to add requirements for amending reports if the laboratory discovers an error has occurred. Adds trailing zero to requirements when calculated adult use cannabinoid or CBD result exceeds 100.0 percent. Amends rule language to change shall to must.

CHANGES TO RULE:

333-064-0110

Reporting Cannabis Test Results ¶

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

(2) A laboratory must ensure that all test report~~musts~~ clearly:¶

(a) Identify for the licensee or registrant:¶

(A) Whether a sample has exceeded an action limit for an analyte in OAR 333-007-0400, 333-007-0410, 333-007-0415, and 333-007-0425 Exhibit A, Tables 3, 4, 8, or 9, or has otherwise failed a test as described in OAR 333-007-0300 to 333-007-0500.¶

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

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

(D) Identification of the test as a compliance test or a quality control or research and development test. ~~Until March 1, 2027, if the test is not for compliance, the report shall~~must indicate clearly on the first page the testing was for quality control or research and development.¶

~~(E) If applicable, a statement that the test was done on a sample from a remediated marijuana item or industrial hemp-derived vapor item. On and after March 1, 2027, identification of the test as a compliance test or quality control or research and development test. If the test is for compliance and meets Oregon compliance test standards in OAR chapter 333, division 7 and these rules, the report must on the first page state "The testing reported is sufficient for Oregon compliance test requirements".¶~~

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

~~(F) On and after March 1, 2027, for potency that was tested multiple times on usable marijuana, as outlined in OAR 333-064-0100, all test results and batch quality control results must be listed on the report.¶~~

~~(G) On and after March 1, 2027, if required in OAR 333-007-0360, OAR 333-007-0140, OAR 333-007-0430, and OAR 333-064-0100, the mean result of primary, duplicate, and replicate samples, as applicable. ¶~~

~~(H) On and after March 1, 2027, if applicable, the relative percent difference (RPD) or relative standard deviation (RSD) of primary, duplicate, or replicate samples as required in OAR 333-007-0410, 333-007-0430, and OAR 333-064-0100. ¶~~

~~(I) On and after March 1, 2027, identification of any failed tests on the first page of the test report. ¶~~

~~(J) On and after March 1, 2027, if applicable for cannabinoid products, the target potency, serving sizes and unit of sale, density or mass, or volume of intended serving sizes and unit of sale as provided to the laboratory under OAR 333-007-0315. ¶~~

~~(K) On and after March 1, 2027, test results and quality control results in a form containing the same or more significant figures as each action level for the analyte being tested in accordance with OAR 333-007-0400, OAR 333-007-0410, OAR 333-007-0415, OAR 333-007-0420, and OAR 333-007-0425 and OAR 333-064-0100 Exhibit C. ¶~~

~~(L) On and after March 1, 2027, quantitative quality control results in percent recovery.¶~~

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

(A) The address of the customer; and¶

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

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

- (a) Into the Cannabis Tracking System (CTS) if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8; and¶
- (b) To the Oregon Health Authority (Authority) electronically at [www.healthoregon.org/ommp](http://www.healthoregon.org/ommp) if performing testing for a registrant, along with a copy of the test order information required in OAR 333-007-0315, regardless of whether the laboratory is also reporting into CTS on behalf of a registrant that is subject to CTS tracking under OAR chapter 333, division 8.¶
- (c) If the laboratory discovers that an error has occurred after reporting, an amended report ~~shall~~must be generated and communicated to the licensee or registrant, the Oregon Liquor and Cannabis Commission (Commission) for licensees, and the Authority for registrants. The laboratory ~~shall~~must ensure that results entered into the CTS are accurate and updated if necessary to reflect the amended report. The laboratory ~~shall~~must ensure that the amended report, communication, and updates to CTS as described in this rule are completed within 48 hours of learning of the error.¶
- (d) The laboratory must have a written procedure for amending test reports when an error is discovered and the error must be corrected in the CTS. Prior to issuing the amended report, the laboratory must supply to the Authority or the Commission: ¶
- (i) A letter from the laboratory's technical manager, or their designee, confirming the laboratory mistake or error and agreeing to the invalidation request;¶
- (ii) Complete sample identification, date and time of sampling event, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;¶
- (iii) Complete description of the error alleged to have invalidated the result(s);¶
- (iv) Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question;¶
- (v) A corrective action plan that contains a cause analysis of the laboratory accident or error, the corrective actions that will take place, and the date the problems will be corrected; and¶
- (vi) An amended test report that clearly identifies the report as an amended report on the first page, as required in 2016 TNI Standard.¶
- (4) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0500 that have not been reported under section (3) of this rule into the ~~Commission's seed to sale tracking system~~CTS if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8.¶
- (5) A laboratory must determine and include on each test report its limit of quantitation (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3, 333-007-0410 Table 4, 333-007-0415 Table 8, and 333-007-0425 Table 9.¶
- (6) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 5:1 and meets identification criteria with a result of "detected." This additional reporting is not required if the laboratory's LOQ is less than or equal to one half of the action level in OAR 333-007-0400 Table 3.¶
- (7) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.¶
- (a) Batch quality control samples are the method blank or negative control and laboratory control sample (LCS) or positive control.¶
- (b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.¶
- (8) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (3) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.¶
- (9) If requested by the Authority, a laboratory must report sampling and testing information to the Authority, in a manner prescribed by the Authority.¶
- (10) If a laboratory's calculated adult use cannabinoid or CBD result exceeds 100.0 percent and the difference between the result and 100.0 percent is within the laboratory's calculated analytical measurement uncertainty, the laboratory may report the result as 100.0 percent with a qualifying statement on the certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100.0 percent is outside the calculated analytical measurement uncertainty, the calculated result ~~shall~~must be reported without correction.¶
- (a) The qualifying statement on the certificate of analysis ~~shall~~must clearly state the calculated value and the laboratory's analytical measurement uncertainty.¶
- (b) For the purposes of calculating relative percent difference (RPD) or relative standard deviation (RSD), a laboratory ~~shall~~must use the calculated result and not the adjusted result described in this rule.¶
- (11) A primary accredited laboratory may subcontract with accredited laboratories to perform required compliance testing. The primary accredited laboratory ~~shall~~must issue the final report.¶
- (a) Accredited, subcontracted laboratories ~~shall~~must validate the results of any sample analysis and report that analysis to their client laboratory within 24 hours of completing the analytical run if the analysis results in a failed

compliance test.¶

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

Statutory/Other Authority: ORS 475C.544, ORS 475C.560

Statutes/Other Implemented: ORS 475C.544, ORS 475C.560

RULE SUMMARY: OAR 333-064-0120: Amends rule to correct that the EPA ID is reported during proficiency testing, not the ORELAP ID. Amends rule to remove language tied to a past date. Amends rule language to add list of prohibited activities during testing and that laboratories must train personnel on this during data integrity training. Amends rule to add clarifications on how to perform rounding of results. Amends rule language to change shall to must.

CHANGES TO RULE:

333-064-0120

Proficiency Testing for Laboratories Accredited for Cannabis Testing

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

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

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

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

(2) For purposes of this rule:¶¶

(a) A PT study is a scheduled PT study or a supplemental PT study.¶¶

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

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

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

(A) The laboratory's name and address;¶¶

(B) The laboratory's ~~ORELAP ID number~~ EPA ID number listed in the ORELAP Data Input and Edit (ODIE) database; and¶¶

(C) The method and analyte codes.¶¶

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

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

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

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

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

(i) <PTRL; or¶¶

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

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

(D) For non-detect results, <PTRL.¶¶

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

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

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

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

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

(5) For pesticide, mycotoxin ~~analysis on or after August 1, 2024,~~ and potency analyses in usable marijuana, a laboratory must use PT samples made with a usable marijuana matrix. If a usable marijuana matrix is unavailable, then a PT sample made with usable hemp matrix may be used with written permission from ORELAP. If a PT sample made with a usable hemp matrix is used for accreditation of potency analysis, then the PT provider must prepare

the sample in usable hemp material itself and may not provide a separate spiking solution with the sample.¶¶

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

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

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

(7) For purposes of this rule a successful PT study means the testing results have been reported according to these rules and evaluated by the PT provider and ORELAP as acceptable.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE SUMMARY: OAR 333-064-0140: Amends rule language to add requirements for initial calibration verification (ICV) and continuing calibration verification (CCV) quality control requirements in Exhibit D, Table 1. Adding a zero to the right of all limits listed in Exhibit D, Table 1.

CHANGES TO RULE:

333-064-0140

Psilocybin Products Sampling Procedures and Testing

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

(2) Sampling.¶

(a) A laboratory must have and follow psilocybin products sampling policies and procedures, accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP), that:¶

(A) Ensure sampling will result in a sample that is representative of the batch being sampled.¶

(B) Require sampling and laboratory personnel to document and collect any information necessary for compliance with these rules, OAR chapter 333, division 333, and any applicable TNI Standards.¶

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

(D) Are appropriate to the matrix being sampled.¶

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

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

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

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

(c) Laboratory personnel that perform sampling must:¶

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

(B) After taking samples:¶

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

(ii) If sampling for a manufacturer required to comply with Psilocybin Tracking System (PTS) tracking under ORS 475A.400, record the sampling and transfer information in the tracking system, as required by the Oregon Health Authority (Authority).¶

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

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

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

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

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

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

(C) Assign a unique identification number for the test batch in accordance with OAR 333-333-7110 and TNI Standard requirements.¶

(D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.¶

(E) Place the laboratory identification code as a durable mark on each sample container.¶

(F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.¶

(f) Combining sample increments.¶

(A) Sample increments collected from the same batch of whole fungi ~~shall~~must be combined into a composite sample and homogenized prior to testing.¶

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

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

- (ii) Increments from a duplicate sample must be combined into a composite sample separate from the primary sample composite sample.¶
- (C) Prior to any testing or subsampling, each composite sample must undergo the laboratory's homogenization process.¶
- (D) If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis.¶
- (3) Compliance testing validity.¶
- (a) When testing a sample for the required chemistry compliance tests as described in OAR 333-333-7040 and 333-333-7050, a laboratory ~~shall~~must comply with additional method validation as follows:¶
- (A) Run a method blank in accordance with TNI Standard requirements to demonstrate the procedure is free of contaminants at or above the limit of quantitation (LOQ).¶
- (B) Run a laboratory control sample (LCS) in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the LCS means percent recovery for all regulated analytes ~~are~~must be within the limits specified in Exhibit D, Table 1.¶
- (C) Calculate a measure of precision within each analytical batch. This may be done by analyzing an analytical duplicate sample or a laboratory control sample duplicate (LCSD) and calculating the relative percent difference (RPD). An analytical duplicate sample is prepared from a second aliquot of material from the same sample to determine variability of measurements within the laboratory.¶
- (D) Run an initial calibration verification (ICV) for each initial calibration in accordance with TNI Standard requirements. Acceptable performance of the ICV means percent recovery for all regulated analytes must be within the limits specified in Exhibit D, Table 1.¶
- (E) Run continuing calibration verification (CCV) in accordance with TNI Standard requirements. Acceptable performance of a CCV means percent recovery for all regulated analytes must be within the limits specified in Exhibit D, Table 1.¶
- (b) When performing a speciation test as described in OAR-333-333-7030, a laboratory ~~shall~~must use any DNA-based approach that has been validated to show acceptable inclusivity, exclusivity, and probability of detection (POD). A laboratory ~~shall~~must comply with additional method validation as follows:¶
- (A) The laboratory must perform initial method validation to include inclusivity and exclusivity testing using whole tissue or cultured organisms. This is to show the laboratory has proficiency with the DNA extraction, replication, and detection processes and can demonstrate the ability to differentiate between the target organism and other organisms that may be found in samples. Nothing in these rules prohibits testing laboratories from possessing *Psilocybe cubensis* for purposes of method validation and testing.¶
- (B) Run a negative control to show laboratory reagents and equipment are not causing false positives.¶
- (C) Run a positive control with each batch to show acceptable performance of the method. Acceptable performance means detection of target DNA sequences in the positive control that has been spiked with *Psilocybe cubensis* genetic material.¶
- (D) Demonstrate acceptable performance as described in the manufacturer's instructions of an internal amplification control (IAC) in each sample analyzed by a polymerase chain reaction (PCR) method. In the case of a positive result for *Psilocybe cubensis* in a sample with an unacceptable performance of the IAC, follow the manufacturer's instructions on interpretation of acceptability.¶
- (4) Compliance testing results ~~should~~may not be adjusted for percent moisture, or on any other basis except to account for extraction and dilution during laboratory preparation.¶
- (5) Calculating RPD and relative standard deviation (RSD):.¶
- (a) A laboratory must use the following calculation for determining RPD:¶
- Relative Percent Difference¶
- $$\%RPD = |(sample - duplicate)| / ((sample + duplicate) / 2) * 100.¶$$
- (b) A laboratory must use the following calculation for determining RSD:¶
- (A) Standard Deviation¶
- $$S = (((x_i - x)^2) / (n - 1))^{1/2}¶$$
- (B) Relative Standard Deviation¶
- $$\%RSD = (S / x) * 100.¶$$
- (c) For purposes of this section:¶
- (A) S = standard deviation.¶
- (B) n = total number of values.¶
- (C) x<sub>i</sub> = each individual value used to calculate mean.¶
- (D) x = mean of n values.¶

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

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

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

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

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

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

(11) When performing calculations, a laboratory may not round any values during intermediate steps of a calculation, except as described in subsection (a) of this section.¶

(a) A laboratory may only round intermediate values to six significant digits after the decimal point.¶

(b) Rounding may only occur after all calculation steps have been completed.¶

(12) A laboratory must have and implement a written policy identifying the following activities as prohibited. A laboratory must train personnel to this policy during the data integrity training required by the TNI Standard. A laboratory is prohibited from the following actions:¶

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

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

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

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

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

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

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

(h) Inappropriately preparing and analyzing quality control samples;¶

(i) Deleting or failing to record quality control data outside acceptance criteria; ¶

(j) Performing improper manual integrations;¶

(k) Concealing a known analytical or sample problem;¶

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

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

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

(o) Performing repeated or additional testing on a sample for the purpose of achieving a preferred result; and¶

(p) Performing repeated or additional testing on a sample for the purpose of preventing the sample from failing for an action limit described in:¶

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

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

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

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

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

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

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

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

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

(b) Notwithstanding subsection (11)(a), it is not a violation of these rules for an accredited laboratory to receive materials containing psilocybin for purposes of establishing instrument calibrations or validating laboratory

processes necessary for testing required under ORS 475A.590 from the following entities:-¶¶

(A) Providers of certified reference materials;-¶¶

(B) Approved or accredited providers of proficiency tests;-¶¶

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

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

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

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

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

NOTE: Attachments referenced are attached to this document. You may view the attachment 333-064-0140.pdf from the Attachments panel. Alternately, you may view the attachments at the following link:

<https://secure.sos.state.or.us/oard/viewAttachment.action?ruleVrsnRsn=340275>

RULE SUMMARY: OAR 333-064-0150: Amends rule language to add requirements for actions a laboratory must take if the laboratory discovers an error after reporting that requires updates to the Cannabis Tracking System (CTS). Amends rule language to change “total potential psilocin” to “total psilocybin equivalent”. Amends rulemaking to add clarifications on what a laboratory will do if it discovers an error after reporting the test results. Adds trailing zero to requirements when calculated potency result exceeds 100.0 percent and that measurement uncertainty must be reported with those test results. Amends rule language to change shall to must.

CHANGES TO RULE:

333-064-0150

Reporting Psilocybin Products Test Results

- (1) For purposes of this rule the definitions in OAR 333-333-1010 apply unless the context indicates otherwise.¶
- (2) A laboratory must ensure that test report ~~must~~ clearly identify for the manufacturer:¶
- (a) Whether a sample has exceeded an action limit for an analyte in OAR 333-333-7050, or has otherwise failed a test as described in OAR 333-333-7030 and 333-333-7040.¶
- (b) The batch unique identification number required under OAR 333-333-7090 and the test batch number associated with the samples tested, as required by OAR 333-333-7110.¶
- (c) Identification of the test as a compliance test or a quality control or research and development test. If the test is not for compliance, the report ~~shall~~must indicate clearly on the first page the testing was for quality control or research and development.¶
- (d) If applicable, a statement that the test was done on a sample from a remediated psilocybin product.¶
- (3) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-333-7030, 333-333-7040, and 333-333-7050, whether or not the laboratory is reanalyzing the sample under OAR 333-333-7120, into ~~PTS~~Product Tracking System (PTS) if performing testing for a manufacturer who is subject to PTS tracking under OAR chapter 333, division 333.¶
- (4) If the laboratory discovers that an error has occurred after reporting a result to a manufacturer or into PTS, an amended report ~~shall~~must be generated and communicated to the manufacturer. The laboratory ~~shall~~must ensure that results entered into the PTS are accurate and updated if necessary to reflect the amended report. The laboratory ~~shall~~must ensure that the amended report, communication, and updates to PTS as described in this rule are completed ~~within 48 hours of learning of~~ by 11:59 a.m. the following day of discovering the error.¶
- (5) The laboratory must report all test results required under OAR 333-333-7030, 333-333-7040, and 333-333-7050 that have not been reported under section (3) of this rule into PTS if performing testing for a manufacturer who is subject to PTS tracking under OAR chapter 333, division 333.¶
- (6) Each potency testing report ~~shall~~must include the results for psilocybin analyte and psilocin analyte expressed in mg/g as well as ~~Total Potenti~~total Psilocybin equivalent in accordance with OAR-333-333-7040.¶
- (a) ~~Total Potential Psilocin~~total Psilocybin equivalent must be calculated as follows:¶
- $$\text{mg/g Total Potenti} \text{total Psilocybin} = \text{equivalent} = 1.4 * \text{mg/g psilocin analyte} + 0.719 * \text{mg/g psilocybin analyte.} \quad \text{¶}$$
- (b) Potency results for whole fungi ~~shall~~must be reported as the calculated values for psilocybin analyte, psilocin analyte, and ~~Total Potenti~~total Psilocybin equivalent as determined in the composite sample.¶
- (c) Potency results for homogenized fungi, psilocybin extract, or edibles ~~shall~~must be reported as the calculated values for psilocybin analyte, psilocin analyte, and ~~Total Potenti~~total Psilocybin equivalent as determined in the primary composite sample.¶
- (7) Each solvent testing report ~~shall~~must include the results for the solvent used by the manufacturer in accordance with OAR 333-333-7050.¶
- (8) Each speciation testing report ~~shall~~must indicate if the batch was positively identified as Psilocybe cubensis.¶
- (9) A laboratory must determine and include on each test report its limit of quantitation (LOQ) and action level for each analyte listed in OAR 333-333-7040 and 333-333-7050.¶
- (10) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.¶
- (a) Batch quality control samples are the method blank and laboratory control sample (LCS) and the positive and negative controls in speciation testing.¶
- (b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.¶
- (c) On and after March 1, 2027, the report must clearly identify any analytes associated with quality control results outside of the acceptance limits defined in OAR 333-064-0140 Exhibit D. in accordance with TNI Standards. The quality control results are the method blank (MB), laboratory control sample (LCS), initial calibration verification

(ICV), and continuing calibration verification (CCV).¶

(d) On and after March 1, 2027, quantitative quality control results must be in percent recovery.¶

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

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

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

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

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

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

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

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

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

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