

ORELAP Update



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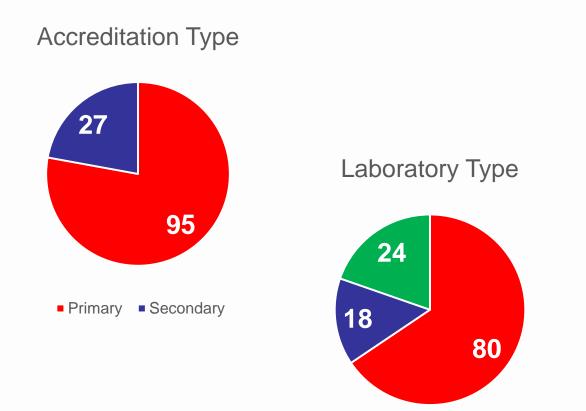
OREGON ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM
Public Health Division

ORELAP in 2022

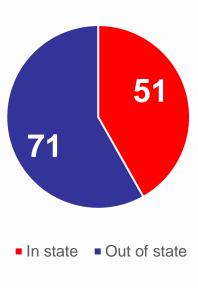
- ORELAP accreditation fee structure changed effective July 15, 2022.
- Actively working on administrative rules regarding accreditation of psilocybin testing laboratories
 - Ballot Measure 109 passed November 2020, ORELAP to begin accrediting psilocybin laboratories in advance of January 2, 2023 start date for Oregon Psilocybin Program license applications.
- Implemented changes to cannabis testing rules in response to SB 96 and HB 3000. Most changes took effect March and July.
 Remaining changes take effect March 1, 2023.
- ORELAP has hired three new assessors!



ORELAP at a glance...



In/Out of state



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■ DW ■ Cannabis ■ Environmental



ORELAP at a glance...

Year-to-date

193 applications40 assessments668 PT uploads2 rulemakings



ORELAP Rulemaking event in 2022

- Changes to Oregon Administrative Rules, Chapter 333, Division 64, creating framework for accreditation of psilocybin testing laboratories.
 - harmonized with Oregon Psilocybin Services (OPS) rules in Chapter 333, Division 333
- Rule advisory committee held on September 12, 2022.
- Public hearing to be held TBD.
- Written comments due TBD.
- Rule adoption ASAP after filing with Secretary of State's office.
- Find more information about the public hearing on the ORELAP webpages.



Psilocybin

- Implementation required by January 2, 2023.
- Final testing and draft laboratory accreditation rules:
 - Potency (HPLC) of Psilocybin analyte, Psilocin analyte, and Total
 Potential Psilocin
 - Speciation test of whole dried mushrooms (PCR)
 - Psilocybe cubensis is the sole allowable species
 - Residual solvents methanol and acetic acid
 - Random and representative sampling of psilocybin products
- More information will be posted on the ORELAP and OPS websites as it becomes available.



Rule Changes that took effect in 2022

- Changes to ORELAP accreditation fees (OAR 333-064-0060)
 - Implemented July 15, 2022
 - Impacts invoices generated after the implementation date
- Changes include increases for application and assessment fees and moving from a 3-tier to a 5-tier system.
- Onsite trip fee for in-state laboratories removed. Out-of-state laboratories still pay all travel costs.
- More information on ORELAP website!



Rule Changes that took effect in 2022



- End control studies
- End ORELAP-SOP-002 Rev 4.2
- Begin ORELAP-SOP-002 Rev 4.3
- Begin Finished Inhalable Cannabinoid Product classification
- Begin New Exhibit B, Table 7, Sampling for concentreates, extracts, finished inhalable products and industrial hemp-vapor item
- Begin fresh-baked cannabinoid edible sampling process
- Change precision requirement (primary/duplicate RPD or RSD for replicate analysis) to 10%
- Begin reporting R&D testing into Metrc
- Begin using new LCS limits including on reports into Metrc. OAR 333-064-0100, Exhibit C
- Begin 7 day harvest lot
- July 1, 2022
- · Begin 50.0lb batch size max
- Begin Delta-8 THC testing
- Begin Mycotoxins testing
- End ORELAP-SOP-001 Rev 4.0
- Begin ORELAP-SOP-001 Rev 4.1

- March 1, 2023
- Begin Heavy Metals testing
- Begin Microbiological testing
- End Water Activity testing for marijuana used to make Concentrate/Extract/Kief

- Changes to Cannabis testing rules (OAR 333-064-0100 and -0120)
- Additional compliance tests
- Changed maximum batch size for usable marijuana
- New LCS criteria

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2021 EPA Method Update Rule Reminder

- Updates to National Pollutant Discharge Elimination System (NPDES) regulations in 40 CFR 136
- Final rule became effective July 19, 2021.
- Changes to the approved methods for NPDES work.
- For Standard Methods, now list methods by publication year rather than edition.
- Footnote 84 under 40 CFR 136.3, Table 1B, specifies use of the most recent QA sections for Standard Methods chemistry methods.
- Laboratories need to update their method references for NPDES during annual renewals! May become a finding in the coming years!



New regulated work?

- PFAS. At this point, seems like SDWA, CWA, and RCRA regulations are inevitable.
- Recommend laboratories start completing PTs now if not already, will likely be added to Fields of Proficiency Testing tables soon.

- Microplastics? California State Water Board published two methods for analyzing microplastics in drinking water.
- CA ELAP has added microplastics to the program's FOA.



Changes to ODIE

- ODIE has an updated user interface. Functionally it is very similar but looks refreshed.
- Major improvement to the response time of the web application.
- Enhancement goals:
 - Create public interface feature to allow anyone (no login required) to search ORELAP accredited laboratories by analyte, method, laboratory name, state, or matrix
 - Provide ability to view PT history to laboratory personnel with an ODIE login



Links

- Oregon Psilocybin Services webpage
 https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx
- ORELAP webpage
 https://www.oregon.gov/oha/PH/LaboratoryServices/EnvironmentalLaboratoryAccreditation/Pages/index.aspx
- TNI Standard Interpretation Requests https://nelac-institute.org/content/NELAP/interpret.php
- NPDES 2021 MUR
 https://www.epa.gov/cwa-methods/methods-update-rule-2021
- Microplastics in drinking water https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/microplastics.html

Health Authority

Questions?

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