



# Oregon

## Environmental Laboratory Accreditation Program

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Department of Environmental Quality, Laboratory Program  
Oregon Health Authority, Public Health Division

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Summary of questions from the March 11 & 22, 2022 information sessions on Psilocybin Accreditation

Q: How will laboratories be accredited if there is no proficiency testing?

A: ORELAP may not be able to arrange for proficiency testing samples at the start of the program. There are other requirements ORELAP will use when making accreditation decisions, including the initial calibration performance, the initial demonstration of capability, the analysis of blanks and control samples, and the maintenance of the instrument. These requirements can be found in the TNI Standard.

Q: What documents does the laboratory have to submit with the application?

A: The laboratory will be directed to submit supporting documents at the last step of the online application process. SOPs, initial demonstrations of capability, detection limits studies, and other documents may be required.

Q: Will a "spore to sale" tracking system be used?

A: Oregon Psilocybin Services (OPS) is currently working on securing a psilocybin product tracking system. ORS 475A (M109) directs OPS to develop a tracking system or work with OLCC to use their vendor, which at this time, is Metrc. OPS will have more information coming soon regarding the status of this process.

Q: Will pesticides testing be required? What about heavy metals? What about moisture and water activity? What about residual antibiotics?

A: Oregon Psilocybin Services (OPS) is currently working on the products and testing rules, which are now in a public comment period from April 1-22, 2022. OPS will also be working on additional proposed rules for the remainder of the products and testing rules later this fall. Pesticides, heavy metals and other testing may be required by OHA as needed. ORELAP is not certain if it will accredit laboratories for pesticides or heavy metals.

Q: Can you combine cannabis and psilocybin assessments?

A: Yes, ORELAP can perform an assessment for both cannabis and psilocybin during the same site visit.

Q: Can a laboratory apply for cannabis and psilocybin accreditation in the same application process?

A: Yes, accreditation for both types of testing may be submitted in the same application.

Q: Is there any interest in shelf-life of psilocybin products?

A: Yes, ORELAP is interested to learn more about shelf stability of psilocybin products, specifically as it relates to appropriate storage and preparation of samples for testing. Oregon Psilocybin Services (OPS) may consider rules related to shelf stability for packaging, labeling and some testing rules. Please visit the OPS website at: [Oregon.gov/psilocybin](https://oregon.gov/psilocybin) for more information.

Q: What are the fees for accreditation?

A: The fees for accreditation can be found in the ORELAP rules at Oregon Administrative Rules (OAR) 333-064-0060. ORELAP charges a non-refundable application fee initially and annually thereafter. ORELAP also charges an assessment fee every other year to defer costs of the onsite assessments. These fees are separate from any licensing fees required by Oregon Psilocybin Services (OPS).

Q: Can we get an email list for networking?

A: We encourage our stakeholders to network with each other, but our program cannot provide a contacts list.

Q: Which volume of the TNI Standard do I need?

A: You will need to purchase Volume 1 of the 2016 TNI Standard. This is the document that describes the laboratory requirements for ORELAP accreditation. Volume 2 is also useful to understand how ORELAP administrates the accreditation program.

Q: Why is cultivation limited to only one species?

A: Oregon Psilocybin Services (OPS) is currently working on proposed rules for product species. The Oregon Psilocybin Advisory Board recommended that OPS begin with one species, *Psilocybe cubensis*, after conducting a research review on psilocybin. The proposed rules will be adopted as final after the public comment period, April 1-22, 2022. Please visit the OPS website for more information: [oregon.gov/psilocybin](http://oregon.gov/psilocybin).

Q: Is there a method for potency?

A: At this time there does not appear to be a reference method available from a methods organization, such as AOAC or USP. The laboratory can be accredited to its own SOP, after validating the method as described in the TNI Standard.

Q: Is ISO 17025 accreditation required?

A: No.

Q: Is DEA or OLCC licensing required?

A: No. OLCC is not involved in the psilocybin program. ORELAP does not require DEA licensing.

Q: Are there any food safety requirements?

A: There are no food safety requirements to be an ORELAP accredited laboratory. Other questions about the psilocybin program and food safety should be directed to Oregon Psilocybin Services (OPS).

Q: Who creates the method for sampling?

A: ORELAP will create a sampling protocol (and accredit laboratories to this protocol) for psilocybin which outlines the minimum requirements for random sampling. The laboratory will create and maintain an SOP describing how they implement those requirements.