

Oregon Psilocybin Services

How to become a licensed laboratory in Oregon

In November 2020, Oregonians passed Measure 109 which is now codified into Oregon law in <u>ORS 475A</u>. This statute establishes a licensing and regulatory framework for psilocybin services in Oregon. Before taking steps to become licensed, please go to: "<u>What is the Oregon Psilocybin Services Act</u>?" and "<u>What are Psilocybin Services</u>?" to learn more.

Under ORS 475A, a licensed laboratory must test psilocybin products produced by a licensed manufacturer. Licensed laboratories must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP). Under OAR 333-333, psilocybin products are required to be tested to confirm the presence of psilocybe cubensis, as well as tested for potency.

General Laboratory License Requirements:



- 1) Must be 21 years of age or older.
- 2) 50 percent of partnership/ownership interests must be held by one or more individuals who have been residents of Oregon for two or more years. Note: This requirement ends in 2025.
- 3) Must be accredited by the Oregon Environmental Laboratory Accreditation Program (ORELAP).
- 4) Must pass a criminal background check.
- 5) Must pass a site inspection as part of the license application process.

Steps to Become a Licensed Laboratory

- 1. You must review and understand statutory (<u>ORS 475A</u>) and administrative rule (<u>OAR, Chapter 333-333</u>) requirements related to a laboratory license.
- 2. You will need to become accredited through the <u>Oregon Environmental Laboratory Accreditation Program (ORELAP)</u>. The process begins by registering for a username in the <u>ORELAP Data Input and Edit (ODIE) system</u>. Once registered, the user can create an initial application for accreditation. The laboratory's application will be reviewed and invoiced. Once the invoice has been paid, ORELAP will arrange for an onsite assessment. The assessment will determine the laboratory's compliance to the accreditation rules and the <u>2016 (TNI) Standards</u>.
- 3. As part of the license application process, you will need to submit a map or sketch of the proposed licensed premises with details described in administrative rules.
- 4. You will need to submit a Social Equity Plan (refer to the OPS Social Equity Plan Resources for resources that can support applicants in meeting this requirement).
- 5. Once you have met all the requirements listed above and have gathered your application materials, you may begin your license application process with OPS. A link to the online application portal will be available on the OPS Laboratory License webpage. You will be required to pay a \$500 application fee.
- 6. Once you have initiated a license application with OPS, you will be sent more information about how to complete the required background check. To prepare, please see this handout on the OPS Background Check Process.
- 7. The OPS team will review your application as quickly as possible and will need to visit your laboratory and perform a site inspection to ensure your premises is compliant with OPS statute and rule requirements.
- 8. If you are approved for licensure, you will be required to pay an annual licensure fee of \$10,000. Applicants who are veterans, receiving social security income, receiving food stamp benefits, or are enrolled in the Oregon Health Plan may

qualify for a reduced annual licensure fee of \$5,000. More information can be found in administrative rules.

How do psilocybin products get to a service center?

- 1) Psilocybin products are cultivated, produced and/or processed by a licensed manufacturer and tracked in a product tracking system.
- 2) Psilocybin products are tested by a <u>licensed</u> laboratory that is accredited by the Oregon Environmental **Laboratory Accreditation** Program (ORELAP). Test results are entered into the product tracking system.
- 3) Psilocybin products are sold or transferred from a licensed manufacturer to a licensed service center and tracked in the product tracking system.



The Oregon Psilocybin Services Team is committed to providing education and technical assistance to our regulated community. If you have any questions about the licensing process, please contact: Licensing.Psilocybin@oha.oregon.gov

For other inquiries about Oregon Psilocybin Services, please contact: OHA.Psilocybin@oha.oregon.gov

