

December 16, 2024

To OPS Licensed Manufacturers and Laboratories,

In November 2024, new and updated administrative rules were adopted and will go into effect on January 1, 2025. This letter describes some of the important changes related to laboratory and manufacturing operations. For a complete description of new and updated rules, please read the [2024 OPS Rules with Tracked Changes](#).

New Term Limits for Worker Permits

The term for new worker permit applications and renewals has been changed from five years to one year. If approved, applicants will now pay the annual \$25 non-refundable permit fee for an annual worker permit. For worker permits approved prior to January 1, 2025, the permit will continue to have a term of five years from the date of initial approval. For all new or renewal permit applications approved on or after January 1, 2025, worker permits will have a term of one year from the date of initial approval.

Updated Dose and Duration Tier

OPS rules on dose, duration, and client to facilitator ratios all use milligrams of psilocybin analyte as a unit of measurement. Minimum Duration of Administration Sessions has been updated to allow clients who consume equal to or greater than 10 mg but less than 15 mg a minimum duration of 3 hours. Clients who consume equal to or greater than 15 mg and less than 25 mg of psilocybin analyte have a minimum duration of 4 hours. For clients consuming less than 2.5 mg of psilocybin analyte, the minimum duration of the administration session will now be 30 minutes for the client's initial administration session and 15 minutes when the client participates in any subsequent administration sessions at the same service center within a 12-month period.

Psilocybin Product Potency Update

Label rules were not amended in 2024; however, OPS has published a [Psilocybin Product Potency Information](#) document and encourages service centers and facilitators to share this document with their clients. This information supports client decisions on selecting a product type and dose that aligns with their intentions for the administration session. The information can also be found on the [Access Psilocybin Services webpage](#) and was added to the Facilitator and Service Center License webpages.

Quality Control Tests

OPS amended rules to allow laboratories greater flexibility in performing quality control tests. OAR 333-333-6030 now allows laboratories to utilize unused product samples for additional tests in certain circumstances. Upon a manufacturer's request, a laboratory may perform quality control test pursuant to OAR 333-333-7150 with unused samples collected and retained for the purpose of performing compliance tests.

How to Surrender a License

A licensee may request to surrender a license by submitting a [License Surrender Request](#). Each individual person identified as a licensee must submit a separate request, including a product plan and client record plan if applicable. The license remains in effect until OPS accepts the surrender. OPS may request additional information and require additional site inspections prior to accepting the surrender.

OPS will review product plans and may require revisions to plans prior to accepting a surrender request. If OPS accepts a surrender request, OPS will notify the licensee in writing of the date of acceptance. The licensee must cease all license privileges on this date through the remainder of the licensing period. The licensee must receive a new license before engaging in any licensed activities.

Thank you for your partnership in the continued administration of the nation's first regulatory framework for psilocybin services.

Sincerely,
The Oregon Psilocybin Services Section

