

Oregon Psilocybin Services Inspection Orientation: Manufacturer Applicant

Overview of Inspection:

A site inspection is conducted to observe and review an applicant's proposed license premises to ensure that it meets all rules requirements for the license applied for as per OAR 333.333.

Oregon Psilocybin Services (OPS) is committed to providing support and guidance for all license applicants. OPS compliance specialists will work with applicants throughout the inspection process to support site inspection readiness and all requirements are communicated.

The site inspection begins with a pre-inspection conference call. This call is conducted to make introductions, talk through the inspection process, confirm scheduling of the site inspection, and ensure everyone is ready for the inspection. At the pre-inspection, OPS has built in an equity pause. This is a short break to express and acknowledge preferences, discuss accessibility needs, and concerns either side may have.

For the day of the inspection, please be sure to schedule enough time for the compliance specialist to review all requirements with you. The estimated length of an inspection will vary depending on complexity and scale of premises but will be approximately 3 hours in duration. The inspection will start with a walk through and a premises plan review. Check the [Premises Plan Checklist](#) to ensure your premises plan is complete and updated with any recent changes that may have occurred.

Timeline for inspection readiness: Applicants have 90 days from the date of application submission to have the premises ready for inspection. At that point, the application will be marked "Incomplete" if not ready, after which you will have 90 more days to make the premises complete. Please communicate with us about any premises development and timeline concerns.

Elements to have ready before an inspection:

- Limited access areas clearly identified (OAR 333-333-4400)
 - *Areas clearly marked by signage. Signage is visible and readable at a reasonable distance. Limited access areas are areas that have or may have psilocybin product or waste.*
 - *Limited access area doesn't need to be a separate room but does need to be labeled.*
 - *Must ensure that all limited access areas of a licensed premises are accessible only to licensee representatives and other personnel authorized to be present.*
- Locked and limited access product storage (OAR 333-333-4510)
 - *Finished psilocybin product must be stored in either a locked enclosed area (with a steel frame door), a locked refrigerator or freezer within a limited access area, or a locked safe within a limited access area.*
- Locked and compliant waste disposal (OAR 333-333-8000)
 - *Psilocybin waste must be stored in a locked waste receptacle or limited access area in the possession of and under the control of the licensee. Waste must be rendered unfit for consumption, securely stored, and disposed of on the licensed premises or transferred to another licensee for disposal. Psilocybin products may be rendered unusable by composting, mixing with inactive ingredients, or any other method which renders the product unfit for consumption but does not pose a safety risk for accidental consumption.*
- Operational alarm system, 2 panic buttons (OAR 333-333-4600)
 - *Should always be activated while closed for business; detect unauthorized entry in the premises and unauthorized activity within; notify the licensee; and have 2 operational panic buttons.*
- Operational surveillance equipment (OAR 333-333-4620)
 - *Including cameras that cover:*
 - *limited access areas, all points of ingress and egress to the premises, all areas where psilocybin products are stored or produced, all psilocybin waste areas (OAR 333-333-4630), all points of ingress and egress to storage, production, and waste areas (OAR 333-333-4650)*
 - *Access to viewing cameras, with ability to print screen shots*
 - *Battery back-up*
- Logs for surveillance maintenance, surveillance outages, limited access areas, and all visitors (OAR 333-333-4660, OAR 333-333-4400)
 - *Surveillance equipment maintenance activity log on the licensed premises to record all service activity including the identity of any individual performing the service, the service date and time and the reason for service to the surveillance system.*
 - *Surveillance equipment outage log on the licensed premises to record all camera outages lasting more than 30 minutes.*

- *Current list of all authorized employees and service personnel who have access to the surveillance system and room on the licensed premises.*
- *Daily log of all employees and permitted visitors who perform work on the licensed premises, except for Authority employees and other state or local government officials acting in an official capacity who have jurisdiction over some aspect of the licensed premises or operation.*
- Sanitary, food-grade, non-reactive surfaces and equipment (OAR 333-333-2020)
 - *Use equipment, counters and surfaces for post-harvest processing that are food-grade and do not react adversely with any solvent being used.*
- Endorsements requested (OAR 333-333-2030)
 - *Must request an endorsement upon submission of an initial application.*
- Complete policies and procedures for endorsements (OAR 333-333-2100)
 - *Applicable to Extraction and Edible endorsements.*
- Fire code compliance for Extraction endorsement (OAR 333-333-2060)
 - *If using methanol or ethanol, a manufacturer must process psilocybin extracts in a room with equipment, including all electrical installations that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code.*
- Required equipment and Personal Protective Equipment for Extraction endorsement (OAR 333-333-2070)
 - *A manufacturer with an extraction endorsement must have an emergency eye-wash station, rinse kit and emergency shower in any room in which solvents other than water are used; and must make appropriate personal protective equipment available to employees.*