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SYNOPSIS of OAR 333-024-0365:

SUBSTANCE OF ABUSE (SOA) TESTING FOR REGISTRATION LABORATORIES

Effective October 4, 1997, facilities/entities performing non-medical, manual, easily portable methods to **screen** for substance of abuse must register annually with the Public Health Division (the Division) of the Oregon Health Authority (OHA). [Prior to October 4, 1997, these entities had to be licensed by the Division as a Substance of Abuse (SOA) screening laboratory.]

Licensed clinical laboratories or laboratories certified or accredited under the Clinical Laboratory Improvement Amendments (CLIA), that perform **only** non-medical SOA testing using manual, easy portable methods, must file a Registration with the Department, pay the \$50, and meet the requirements of OAR 333-024-0365. A CLIA laboratory certified for toxicology testing, and inspected for the same manual method used for their medical and non-medical testing, does not need to obtain a separate Registration, but must follow the requirements of OAR 333-024-0365 for the non-medical testing.

REGISTERED ENTITIES ARE EXEMPT FROM:

- On-site survey
- Proficiency testing
- Other extensive regulations

ENTITIES ARE REQUIRED TO:

- File a registration form with the Division prior to test performance; an entity may be an individual, partnership, corporation, company, district, or local/county/state agency; an entity may be multiple sites under common ownership.
- Provide the location address and contact individual for all testing sites operated by the entity.

-Pay the Division a registration fee of \$50 per entity, per year; fee cycle is January 1st through December 31st.

-Post evidence of registration with the Division in view of the clients, at each location where SOA testing occurs.

-Establish and follow chain of custody procedures.

-Use only tests\kits approved by the Food and Drug Administration (FDA).

-Follow manufacturer's instructions for test performance (including, but not limited to, quality control and temperature, storage and testing requirements).

-Assure appropriate training of testing personnel by the test manufacturer.

-Submit the same specimen used to perform the drug screen, for confirmation testing, if the test result may be used to deprive or deny any client any employment or benefit or may otherwise result in adverse employment action (to a licensed clinical laboratory authorized by the Division to perform SOA confirmation tests).

-Assure that specimens sent to reference laboratories outside of Oregon for confirmation testing are sent only to laboratories which meet or exceed Oregon law.

-Inform the Division within 30 days of changes in entity ownership (requires re-registration) and additions or deletions of on-site testing locations authorized to test for substances of abuse under the entities' registration.

-The entity must be prepared to provide proof to a court of law that they meet the above requirements. This means each entity location must document evidence they meet or exceed each requirement and maintain the documentation for an unspecified length of time. The burden of proof is on the testing entity.

-Refer to the complete OAR for more specific information on requirements.

This document is available in alternate formats by calling 503-693-4100.