

Extracted from the full Clinical Laboratory Rule 333-024

333-024-0365

Substance of Abuse Registration

(1) It shall be unlawful for any entity to perform any on-site test for non-medical substance of abuse screening tests prior to filing a registration form with the Division and payment of the registration fee, except laboratories:

- (a) Owned and operated by the U.S. Government;
- (b) Performing pure research;
- (c) Performing substance of abuse tests for forensic purposes only;
- (d) Performing substance of abuse tests from autopsy specimens;
- (e) Identified as teaching facilities only training students in test performance;
- (f) Owned and operated by the Oregon State Police performing substance of abuse screens for forensic purposes.

(2) SOA registration is not transferable to another entity.

(3) It shall be unlawful for a registered substance of abuse entity to perform medical testing.

(4) Clinical and SOA screening laboratories must meet the requirements under (5)(e) of this rule when performing tests which qualify for SOA registration.

(5) Registration shall be on a form provided by the Division and shall contain:

- (a) The entity name and address;
- (b) Name of legal owner and tax identification number;
- (c) Telephone number;
- (d) Name of individual contact at each on-site facility operated by the entity; and
- (e) Signature of the operator certifying that:

(A) Only SOA kits approved by the Food and Drug Administration (FDA) or alcohol screening tests that meet the requirements of the conforming products list found in the **United States Department of Transportation National Highway Traffic Safety Administration Docket No. 94-004** and meet the standards of the **United States Department of Transportation Alcohol Testing Procedure, 49 C.F.R. part 40**, in effect on October 23, 1999, are used;

(B) Tests are administered according to the manufacturer's package insert;

(C) Custody chain procedures are written and followed;

(D) Operators of the SOA on-site screening facility are trained in the use of the SOA screening tests by the manufacturer; and

(E) When the SOA on-site facility obtains a positive result on a specimen and the entity indicates that the test result is to be used to deny or deprive any person of employment or any benefit, or may otherwise result in adverse employment action, the same specimen shall be submitted to a clinical laboratory licensed under ORS 438.110 or 438.150, or certified under the **Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42.U.S.C.201 and 263a** for that testing, or an equivalent out of state laboratory and the presence of a substance of abuse confirmed, using a different analytical method, prior to the release of the on-site test result.

(6) Evidence of registration with the Division shall be posted at the entity location shown on the registration form and at each on-site facility.

(7) The annual fee for filing a registration form with the Division is \$50 for each entity. The fee cycle shall be January 1 through December 31, beginning 1998.

(8) All monies received by the Division for the registration of SOA entities shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0365.

(9) A list of registered entities is available, upon request, from the Division.

(10) SOA entities may examine specimens submitted by persons other than medical personnel and shall report the result of any SOA test to the person or company who requested the test except as indicated in number (11) of this rule.

(11) A copy of the SOA test results must be provided to the employee or pre-employee from whom the specimen was collected, after the employee or pre-employee submits a written request and proof of identity to the registered SOA entity.

(a) When a written request is given to the SOA entity in person:

(A) The employee or pre-employee must present two proofs of identity to the registered SOA entity, which must include one of the following picture identification cards: state driver's license, state identification card, passport or a resident alien card from the U.S. Department of Immigration and Naturalization Service.

(B) The employee or pre-employee must sign and date a form for release of laboratory records.

(b) When a written request for SOA test results is received by mail:

(A) The request must be accompanied by a signed and dated form for release of laboratory test results and a notarized statement of the employee's or pre-employee's identity and mailing address.

(B) The laboratory will make a copy of the pertinent SOA test results and send this copy by registered or certified mail, or other bonded courier that would assure the confidentiality of the results, to the address requested by the notarized statement.

(C) A copy of the signed release form and picture identification or the notarized statement, shall be maintained by the registered SOA entity for two years.

Stat. Auth.: 438.435

Stats. Implemented: 438.435

Hist.: HD 13-1997, f. & cert. ef. 10-16-97; OHD 10-1999(Temp), f. & cert. ef. 11-26-99 thru 2-22-00; administrative correction 3-17-00; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00