

November 14, 2012

TO: Substance of Abuse (SOA) Registration Entities

FROM: Rita A. Youell, Program Manager
Laboratory Compliance Section

RE: 2013 SOA Registration; Exceptions to the SOA Registration

Please be aware that your current 2012 SOA Registration expires on 12/31/12. Therefore to perform non-medical employment testing for substances of abuse in 2013 you must re-apply for the 2013 Registration. For your convenience a 2013 SOA Registration re-application form has been included in this mailing.

Did you know that Oregon law provides exceptions to the SOA Registration requirement? If you qualify for an exception due to one of the following conditions you need not re-apply:

- 1) Your lab has 'Toxicology' listed on your Clinical Laboratory Improvement Amendments (CLIA) Certificate of Compliance or Certificate of Accreditation (OAR 333-024-0315(4)(c)); *or*
- 2) Your lab is performing a combination of medical SOA testing and manual non-medical SOA screens. This implies you have a current CLIA Certificate for your medical SOA testing (OAR 333-024-0315(11)).

The Laboratory Compliance web page for SOA Registration labs has more information and forms pertaining to the SOA Registration Program. Visit <http://public.health.oregon.gov/LaboratoryServices/ClinicalLaboratoryRegulation/Pages/soalabs.aspx> to view and print this information.

SOA Registration Form

January 1, 2013 through December 31, 2013

56700 58711 2145 \$50.00

Laboratory Compliance Section TEL: 503 693-4125
 Oregon Public Health Division FAX 503-693-5602
 Oregon Health Authority TTY 971-673-0372
 www.healthoregon.org/lcqa

Renewal

State # _____

New Re-open **Complete each numbered item below:**

- ▶ Instructions: Complete all numbered entries through item #15. Read and understand the attestation statement prior to signing. Follow instructions listed in item #15 for submitting the Registration fee.

1. Name of Registration Entity _____

2. Main Site Address - street, city, state, zip code _____

3. Mailing address if different _____

4. Entity Owner: (legal name) _____

5. Contact name for main location, including phone # _____

6. Federal Tax ID # _____

7. Telephone # _____

8. FAX # _____

9. Testing to occur at one fixed location? Check box if 'yes' Testing to occur at Multiple locations? Number of locations: _____ List additional testing locations on the Additional Testing Locations form.

10. Name of SOA test kit(s) used: _____

11. Name of kit manufacturer(s): _____

12. Estimated annual test volume (12 months): _____

Attestation Statement: As Entity Operator for this entity, I certify that the entity indicated above and its staff will meet the following requirements during the term of this substance of abuse registration:

- 1) Only SOA screening kits approved by the FDA, or alcohol screening kits approved by the U.S. DOT as defined by the National Highway Traffic Safety Administration Docket No. 94-004, Notices 2, 3 and 4 published in the Federal Register, are used to test clients; Tests are administered according to the manufacturer's package insert;
- 2) Chain of custody procedures are written and followed;
- 3) Operator of the SOA on-site screening facility is trained by the manufacturer in the performance of the SOA screening test kit;
- 4) Confirmation tests are performed on the same specimen used for screening, by a laboratory possessing a valid CLIA certificate, or an equivalent out of state laboratory, by a different analytical method, when a positive screen is obtained and the test results are to be used to deny or deprive any person employment or any benefit, or may otherwise result in adverse employment action.

The original signature of the Entity Operator is Required:

13. Signature of Entity Operator _____

(Date) _____

14. Print name of operator _____

Registration fee and payment information:

15. Submit SOA Registration fee of \$50.00 check payable to Department of Human Services

Attach payment to your completed Registration form and mail to:

Oregon Public Health Division/Financial Services PO Box 14260 Portland OR 97293-0260