

Testing for Substances of Abuse

333-024-0305

Purpose and Scope

OAR 333-024-0305 through 333-024-0365 are for the purpose of carrying out ORS 438.435 regarding substance of abuse testing in order to protect the people of the State of Oregon. OAR 333-024-0315 through 333-024-0350 establishes a regulatory program for laboratories performing medical testing or non-medical testing by automated methods to ensure the quality of testing. OAR 333-024-0360 sets standards for substance of abuse testing in correctional institutions or programs. OAR 333-024-0365 establishes a registry for entities performing non-medical substance of abuse screening using easily portable screening tests.

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5), ORS 438.435(6) & HB 3098 B-Engrossed

Stats. Implemented: ORS 438.050, ORS 438.130 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0310

Definitions

(1) "Benefit" means, but is not limited to, eligibility for insurance or employment, access to or participation in a drug rehabilitation or mental health program, parole or probation, school attendance or attendance in school activities.

(2) "Chain of custody" or "custody chain" means the handling of specimens in a way which supports legal testimony to prove that the sample integrity and identification of the sample have not been violated, as well as the documentation describing these procedures from specimen collection to final report.

(3) "Confirmatory test" means a highly specific test to identify a substance of abuse or metabolite after a positive screening, based on a different analytical method than that of the initial screening test, at or below the cutoff concentration used for the screening test.

(4) "Control" means a material, the expected testing results of which are known, which is analyzed to ensure that the expected results are obtained.

(5) "Cutoff concentration" means the mass of a substance of abuse per unit volume of specimen, at or above which a test result is considered positive.

(6) "Director of a substances of abuse screening laboratory" or "Director" means the person who plans, organizes, directs and participates in any or all of the technical and administrative operations of a substances of abuse laboratory, including but not limited to reviewing laboratory procedures and their results, and the training and supervising of laboratory personnel.

(7) "Drug control manager" means the individual who works for the inspector general of the Department of Corrections, and oversees drug interdiction efforts of the Oregon Department of Corrections. This includes supervision of urine drug screening.

(8) "Easily portable screening test" means manual, non-automated, substance of abuse methods\kits.

(9) "Entity" means an individual, partnerships, corporation, company, district, local\county\state agency. An entity may be multiple sites under common ownership.

(10) "Local correctional facility" means any institution or facility used specifically for the confinement of inmates operated by a city or county.

(11) "Medical testing" means any test performed at the request of a physician, dentist, or other licensed health care professional for diagnosis and treatment or assessment of health, including testing for rehabilitation or placement into a rehabilitation or mental health program.

(12) "Non-medical testing" means substance of abuse (SOA) screening not for diagnosis and treatment or assessment of health, with or without an order from a

physician, dentist or other licensed health care professional, including but not limited to, employment, pre-employment, on the job accident or injury, screening of students in schools, testing for insurance eligibility or eligibility for plasmapheresis.

(13) "Operator of a substance of abuse on-site screening facility" or "operator" means the person who plans, organizes, directs and participates in any or all of the technical and administrative operations.

(14) "Owner of a substances of abuse screening laboratory" or "Owner" means a person who owns the laboratory, or the State, county or municipality operating the laboratory, or the owner of any institution operating the laboratory or any non-profit organization operating the laboratory.

(15) "Parole, probation and post-prison supervision" means any program operated for offenders by the Department of Corrections or local correctional agencies.

(16) "Proficiency testing" means performance of tests on specimens whose expected results are unknown to anyone in the laboratory, known only to an external agency, and later revealed to the laboratory as an aid to laboratory improvement and/or a condition of licensure.

(17) "Quality control" means methods used to monitor the performance of laboratory tests to detect errors and prevent the reporting of incorrect results.

(18) "Screening" means performing initial tests designed to separate substances of abuse at a particular minimum concentration from those below that minimum concentration (positive versus negative).

(19) "Special category laboratory" means a laboratory that initially screens urine, blood, or other body fluids for substance of abuse, but does not perform confirmation testing by any method.

(20) "Specimen" means body fluids obtained from a live person.

(21) "Standard" means an authentic sample of the analyte of known purity, or a solution of the analyte of a known concentration.

(22) "State correctional facility" means any institution operated by the Oregon Department of Corrections.

(23) "Substances of abuse" or "SOA" means ethanol and controlled substances, except those used as allowed by law and as defined in ORS chapter 475 or as used in ORS 689.005.

(24) "Substances of abuse on-site screening facility" or "on-site facility" means a location where on-site tests are performed on specimens for the purpose of screening for the detection of substances of abuse.

(25) "Substances of abuse on-site screening test" or "on-site test" means a substance of abuse test that is easily portable and is approved by the Food and Drug Administration for commercial distribution or an alcohol screening test that meets 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 meets the standards of the **United States Department of Transportation Alcohol Testing Procedure, 49 C.F.R. part 40**, in effect on October 23, 1999.

(26) "Substances of abuse screening laboratory" or "SOA laboratory" means a facility where initial biochemical examinations are performed on a specimen for the purpose of screening for the detection of substances of abuse for medical purposes or non-medical purposes by automated methods. This includes licensed clinical laboratories screening for substances of abuse.

(27) "Substance of abuse testing program manager" means an individual who is responsible for all aspects of SOA testing in the facility including the quality control, proficiency testing, method selection, equipment maintenance, training, record keeping, and qualifications of individuals performing substance of abuse testing at each state or local correctional facility or parole, probation office site.

[Publications: The publication(s) referenced in this rule are available from the agency.]

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5) & ORS 438.435(6)

Stats. Implemented: ORS 438.050, ORS 438.130, ORS 438.320 & ORS 438.435
Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994,
f. & cert. ef. 7-20-94; 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

333-024-0315

Licensure

(1) It shall be unlawful:

(a) For any owner or director of a SOA or a clinical laboratory to perform medical or automated non-medical SOA screening tests without a license issued under this rule unless they have been certified for that testing under the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, 42.U.S.C. 201 and 263a;

(b) For any person to serve in the capacity of director of an SOA screening laboratory without being qualified as a laboratory director under OAR 333-024-0320(1).

(2) OAR 333-024-0305 through 333-024-0350 apply to all SOA screening laboratories and laboratory personnel within the State of Oregon, except:

(a) Laboratories screening for SOA operated by the United States Government;

(b) Laboratories screening for SOA operated and maintained solely for research or teaching purposes, and that involve no direct patient or public health services;

(c) State Police laboratories screening for SOA as a part of the criminal justice system;

(d) Special category laboratories operated by state or local correctional agencies to monitor inmates and offenders on parole, probation, or post-prison supervision. These special category laboratories must follow the provisions of OAR 333-024-0360.

(3) The Division shall issue and renew licenses to the owners of laboratories screening for SOA who demonstrate to the satisfaction of the Division that:

(a) The SOA laboratory is in compliance with ORS 438.435;

(b) The SOA laboratory is equipped to perform within the scope of its license;

(c) The SOA laboratory meets the standards of the Division for safety, sanitary conditions, plumbing, ventilation, handling of specimens, maintenance of equipment and requirements of general hygiene to ensure protection of the public health.

(4) Requirements for license application; fees, exemptions, expiration; and renewal are as follows:

(a) The application for a license for an SOA screening laboratory shall be made on forms provided by the Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the laboratory, or in the case of a county or municipality, by the public official responsible for operation of the SOA laboratory, or in the case of an institution, by the administrator of the institution. The application shall contain the names of the owner, the director or directors of the laboratory, the location and physical description of the SOA laboratory, and such other information as the Division may require;

(b) Laboratories must pay an annual or biennial, non-refundable license fee, prior to issuance of a license, as described in OAR 333-024-0012(5)(c);

(c) A laboratory certified in toxicology for medical substance of abuse testing under the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 -- Laboratory Requirements**, may also perform that testing for non-medical purposes. No separate substance of abuse screening license or registry is required;

(d) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 of the one or two year cycle following the date of issuance and shall be renewable in the manner prescribed by the Division;

(e) All monies received by the Division for the licensure of SOA screening laboratories shall be credited to the Division account and shall be used for payment of the expenses of the Division in administering OAR 333-024-0005 through 333-024-0350.

(5) A license issued to the owner of an SOA screening laboratory shall show on its face the names of the owners and directors, the location of the laboratory and the laboratory specialty authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.

(6) A license issued to the owner of an SOA screening laboratory is not transferable. The license of the SOA laboratory is voided 30 days after a change of its director if it has only one director or if all directors change or a change in the ownership or in the location of the laboratory. In the case of death of a director, the Division shall be notified within five working days. The laboratory shall have 30 days to obtain another qualified director.

(7) Subject to ORS 183.310 to 183.550, the Division may refuse to issue or renew the license or may suspend or revoke the license of any SOA laboratory, if it finds that the owner or director has:

(a) Intentionally made false statements on an application for an SOA laboratory license or any other documents required by the Division, or made any misrepresentation in seeking to obtain or retain a license;

(b) Demonstrated incompetence as defined in OAR 333-024-0325;

(c) Intentionally falsified any report;

(d) Referred a specimen, for examination, to an unlicensed clinical or SOA laboratory in this state, or a laboratory out of state not certified by the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 -- Laboratory Requirements**, or an equivalent out of state laboratory, unless the laboratory is exempt under section (2) of this rule;

(e) Misrepresented the scope of laboratory service offered by the SOA laboratory or the laboratory specialty authorized by the license;

(f) Rendered a substances of abuse report performed in another laboratory without designating the name and address of the laboratory in which the test was performed;

(g) Knowingly had professional connection with or permitted the use of the name of the licensed laboratory or its director by a laboratory which is required to but has not obtained a license;

(h) Failed to perform or cause to be performed within the time specified, analysis of test samples as stated in OAR 333-024-0340 or failed to report on the results of such analysis within the specified time;

(i) Failed to permit within a reasonable time the entry or inspection as stated in OAR 333-024-0340(2) and (4);

(j) Failed to continue to meet the requirements of this rule, inclusive; and

(k) Violated any provision of OAR 333-024-0305 through 333-024-0350.

(8) Owner shall be responsible for all aspects of the laboratory.

(9) The substance of abuse screening laboratory must be in compliance with requirements of the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 -- Laboratory Requirements**, if medical testing for substances of abuse is performed.

(10) Entities performing only manual, non-automated SOA screens using easily portable screening tests must register with the Division and meet the requirements at OAR 333-024-0365.

(11) Licensed clinical laboratories or SOA screening laboratories performing a combination of medical and manual, non-medical SOA screens are not required to register with the Division and must meet the requirements of OAR 333-024-0365(5)(e) when performing tests which qualify for SOA registration.

(12) Licensed clinical laboratories performing only manual, non-medical SOA screens using easily portable screening tests must register with the Division and meet the requirements of OAR 333-024-0365.

(13) Laboratories certified under the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations, Part 493 -- Laboratory Requirements**, that perform medical and non-medical substance of abuse screening, must comply with 333-024-0305 through 333-024-0350 and 333-024-0365(5)(e).

[Publications: The publication(s) referenced in this rule are available from the agency.]

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), (5) & (6) & ORS 341, 1999
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Stats. Implemented: ORS 438.050, ORS 438.130 – ORS 438.160 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97; OHD 5-1999, f. & cert. ef. 7-30-99; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0320

Qualifications and Responsibilities of Directors

(1) The director of a substances of abuse screening laboratory shall meet one of the following qualifications:

(a) Is a pathologist certified in clinical pathology by the American Board of Pathology, the American Osteopathic Board of Pathology, or is eligible for such certification;

(b) Is a physician with two or more years of clinical chemistry experience, with one year in toxicology;

(c) Has an earned degree of Doctor of Science (ScD), Doctor of Public Health (DrPH) or Doctor of Philosophy (PhD) in chemistry or biochemistry and has two or more years of clinical chemistry training or experience with one year in toxicology;

(d) Is certified or is eligible for certification by the American Board of Clinical Chemistry or by the American Board of Forensic Toxicology;

(e) Has an earned master of science degree in medical technology, chemistry, or biochemistry and has three or more years of clinical chemistry training or experience, with one year of pertinent experience in toxicology;

(f) Has a bachelor of science, bachelor of technology or bachelor of arts degree in medical technology, chemistry or biochemistry, and has four or more years of clinical chemistry training or experience, with one year experience in toxicology;

(g) Has directed substance of abuse screening for at least 12 months within the four years preceding January 1, 1987, and has at least two years of pertinent experience in toxicology.

(2) The director of an SOA screening laboratory shall be responsible for the quality of the work. This shall include, but not be limited to, the following:

(a) Monthly review and documentation of quality control data;

(b) Review and documentation of external proficiency testing within 30 days of receipt of the final report;

(c) Review and documentation of procedure manuals and relevant texts initially and also whenever there is a change in method or policy;

(d) Validation of new procedures prior to reporting test results;

(e) Review and documentation of preventive maintenance of equipment;

(f) Review of additional quality assurance items;

(g) Assure that qualified technical personnel perform the tests; and

(h) Assure the competency of all testing personnel annually.

(3) The director of an SOA screening laboratory shall require the submitter to indicate the need for confirmatory testing as described in ORS 438.435(6).

(4) A person shall not serve individually as director of more than five substances of abuse screening laboratories.

(5) Those individuals qualifying under 333-024-0320(1)(g) must have applied to the Division by January 1, 1989.

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5) & ORS 438.435(6)

Stats. Implemented: ORS 438.210, ORS 438.220 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0325

Incompetence

An SOA laboratory owner or director has "demonstrated incompetence" if there is:

(1) Repeated error demonstrated in the performance of laboratory tests or procedures or the results thereof;

(2) Failure to comply with the requirements of OAR 333-024-0335 and 333-024-0340 relating to internal and external quality control;

(3) Failure to comply with ORS 438.435 or any regulations pertaining to the laboratory;

(4) Work assigned to personnel not qualified to perform in that specialty;

(5) Repeated erroneous reporting of test results.

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5) & ORS 438.435(6)

Stats. Implemented: ORS 438.160 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92

333-024-0330

Specimen Collection, Chain of Custody, Records, and Reports

(1) The specimen container shall be clean, tightly sealed and free of any interfering substance. It shall be transported and stored in such a manner as to preserve the integrity and security of the specimen.

(2) The specimen container shall be permanently labeled with time and date of collection and atleast one of the following:

(a) The name of the person from whom the specimen was taken, if available;

(b) Social security number;

(c) Employee number;

(d) Unique identifying number.

(3) The initial request form, used by the person requesting the test, must have a statement indicating whether, if positive, the test results are to be confirmed as required under ORS 438.435(7).

(4) For those specimens requiring a confirmatory test, a record shall be made of the following:

(a) Time and date of collection;

(b) Identity of the individual receiving the specimen; and

(c) Manner by which the specimen was sent to the laboratory, including the name of the commoncourier or the individual delivering the specimen.

(5) Any laboratory receiving or referring the specimen shall keep for a minimum of two years a record of the following:

(a) The condition under which the specimen was collected or received and results of tests or information to rule out adulteration of the specimen;

- (b) The date, time and one of the unique identifications from the specimen label;
 - (c) Time and date received and referred;
 - (d) Laboratory accession number;
 - (e) Condition of the specimen;
 - (f) The name of the company or individual requesting the test; and if positive, whether the specimen requires confirmatory testing as described in OAR 333-024-0345(1);
 - (g) The type of test performed;
 - (h) The results of the tests and controls in units of measurement where applicable; and the type and concentration of standard(s) used in testing;
 - (i) Storage of specimen before and after screening;
 - (j) The signature, initials, or identification of the testing personnel;
 - (k) Date and time the tests were completed; and
 - (l) The name of the clinical laboratory performing the confirmatory testing if required under OAR 333-024-0345(1).
- (6) Clinical and substance of abuse screening laboratories may examine specimens submitted by persons other than medical personnel authorized by law and shall report the result of any test to the person or company who requested the test except as indicated in number (7) of this rule.
- (7) 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 laboratory.
- (a) When a written request is given to the laboratory in person:

(A) The employee or pre-employee must present two proofs of identity to the laboratory, 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 laboratory for two years.

Stat. Auth.: ORS 438

Stats. Implemented: ORS 438.310, ORS 438.320 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; 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

333-024-0335

Internal Quality Assurance

(1) Laboratory procedure manuals and relevant texts of appropriate current laboratory methods shall be available for the use of the personnel in the laboratory.

(2) Each instrument system shall be calibrated according to the manufacturer's specifications and the calibrations shall be checked and recorded at intervals compatible with the proper operation of that instrument.

(3) Quality control requirements:

(a) Automated: At least one positive and one negative standard or control shall be included with the frequency recommended by the manufacturer; or at a frequency documented to assure the stability of the analytical method; but no less than once per day of testing.

(b) Manual:

(A) Test kits without positive and negative procedural controls, the laboratory must run at least one positive and one negative standard or control each day of testing for each analyte;

(B) Test kits with positive and negative procedural controls, the laboratory must run at least one positive and one negative standard or control with each lot/shipment and at least once per month for each analyte tested. Results of internal procedural controls must be documented with each sample tested.

(4) A permanent logbook or computer printout shall be kept and include patient/client name or unique identifier, date of test performance, quality control, reagent lot number, temperature, testing analyst, screening result and evidence for referral for confirmation, if applicable.

(5) Each analyst must annually demonstrate testing proficiency and interpretive competency for each analyte tested by proficiency testing internal blind samples.

(6) For each method, the minimum detectable limit for each substance tested must be on the report or in a letter of agreement between the laboratory and the client.

(7) Cutoffs at the minimal detectable range must be verified with a control when there is a lot change or major instrument maintenance.

(8) For each method, whether automated or manual, data shall be recorded and available to document the results on routine precision.

(9) Limits for controls shall be clearly stated and recorded. The corrective action taken when analyses are outside these control limits shall be clearly stated and recorded. The control limits shall be set so that reliable results are assured. Values for standards shall be clearly stated and recorded.

(10) Quality control results shall be recorded and retained in the laboratory for 2 years.

(11) Solid and liquid reagents, reagent solutions, standards and controls, if prepared in the laboratory, shall be calibrated and dispensed in a manner so as to ensure accuracy of results.

(12) All reagents and solutions shall be labeled to indicate identity, preparation date, expiration date, lot number, and storage conditions. No reagents or solutions may be used beyond their expiration date.

(13) The laboratory shall have a written procedure for chain of custody.

Stat. Auth.: ORS 438

Stats. Implemented: ORS 438.320 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-95; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0340

External Quality Control (Proficiency Testing Program and On-Site Inspections)

(1) Licensed SOA laboratories shall:

(a) At the laboratory's own expense, be required to participate satisfactorily in the proficiency testing programs of the College of American Pathologists, or the American Association of Bioanalysts, or such other substantially equivalent testing program as

may be approved by the Division involving substances of abuse testing and make available to the Division all test results;

(b) Be required to participate satisfactorily if required in the proficiency testing programs conducted by the Division involving substances of abuse testing;

(c) Analyze test samples submitted by the Division prior to, during, or subsequent to inspection if requested to the Division;

(d) Achieve satisfactory results on test samples in agreement with reference laboratories or within stated acceptable limits and which results shall be reviewed by the Division. Continued or consistent failure two out of three periods may result in the laboratory's license being withdrawn by the Division until satisfactory performance is demonstrated; and

(e) Ensure that proficiency samples are tested by regularly assigned personnel using routine methods. A specified time shall be allowed for such testing and reporting of results.

(2) Biennial on-site inspections may be conducted by representatives of the Division at reasonable times during the laboratory's normal business hours without advance notice. The representative shall inspect the facilities, personnel policies, procedures, materials, staff qualifications, equipment and records.

(3) The owner or director of an SOA laboratory may be required to submit reports on the operations and procedures of the laboratory.

(4) Additional inspections may be performed without notice to verify correction of deficiencies, investigate complaints, review unsatisfactory proficiency testing and verify personnel qualifications or other monitoring of compliance with OAR 333-024-0305 through 333-024-0350.

Stat. Auth.: ORS 438

Stats. Implemented: ORS 438.320 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 20-1994, f. & cert. ef. 7-20-94; HD 6-1995, f. & cert. ef. 9-13-95; HD 13-1997, f. & cert. ef. 10-16-97

333-024-0345

Confirmatory Testing

(1) When the substances of abuse screening laboratory obtains a positive test result and the submitter indicates the result is to be used to deprive or deny any person any employment or any benefit, that same specimen must be submitted and confirmed prior to the release of the screening results. When performed within the State of Oregon, the confirmatory testing shall be by a clinical laboratory licensed under ORS 438.110 and 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. The confirmatory testing shall be as described in section (4) of this rule.

(2) The administrator of the Division shall appoint a substances of abuse methods panel to recommend approval of methods used to confirm the presence of substances of abuse. The panel shall be composed of individuals from laboratories performing substances of abuse testing and shall include, but not be limited to, representatives from the Oregon State Police Crime Laboratory, laboratories licensed under ORS Chapter 438, and the Oregon Health Sciences University.

(3) Any scientifically tested method for substances of abuse analysis may be submitted to the Division, for approval, by written request from a manufacturer, laboratory, or other party. Each candidate method shall be evaluated as to its capacity for accuracy by the panel, with recommendation based thereon, by one or more of the following means:

(a) Government or independent studies of the method's accuracy;

(b) Comparative data on proficiency test performance of various methods;

(c) Application of the method by panel members in performance of analysis; or

(d) Other means as determined by the Division.

(4) The following methods of chemical analysis to determine substances of abuse have been approved:

(a) Chromatography;

(b) Immunoassay;

(c) Spectroscopy;

(d) Mass spectroscopy.

(5) The confirmatory test shall be performed by a different analytical method from that used for the initial screening test.

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5) & ORS 438.435(6)

Stats. Implemented: ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 5-1992, f. & cert. ef. 5-15-92; OHD 9-2000, f. & cert. ef. 11-3-00

333-024-0350

Equipment and Facilities

(1) All equipment shall be maintained in good working order, checked routinely, and precisely calibrated.

(2) Work bench space shall be ample, clean, well-organized, well-lighted, and convenient to sink, water and electrical outlets.

(3) The SOA laboratory shall be ventilated to protect the health of the personnel and patients against accidental release of hazardous vapors or aerosols.

(4) The premises shall be free from unnecessary physical, chemical, and biological hazards.

(5) Electrical equipment shall be maintained in a safe condition with regards to shock and fire hazards. All electrical equipment, except battery operated, shall be grounded. Protective fuses shall not be bypassed.

(6) Caustic, explosive and flammable materials shall carry labels to indicate their nature and shall be placed in containers and stored in locations which are suitable to ensure stability, purity, and safety as is necessary regarding the material involved.

Stat. Auth.: ORS 438

Stats. Implemented: ORS 438.320 & ORS 438.435

Hist.: HD 28-1988, f. & cert. ef. 12-7-88; HD 6-1995, f. & cert. ef. 9-13-95

333-024-0360

Special Category Laboratories

(1) The rules in this section set standards for special category screening laboratories, as authorized in ORS 438.435(4), (6) and (7). These rules apply to the testing of inmates within state and local correctional facilities and to the testing of offenders on parole, probation, or under post-prison supervision.

(2) Special category laboratories as defined in this rule must use only manual or automated substance of abuse screening methods approved by the U.S. Food and Drug Administration. Any alcohol screening test must 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 meets the standards of the **United States Department of Transportation Alcohol Testing Procedure, 49 C.F.R. part 40**, in effect on October 23, 1999.

(3) Individuals who perform screening tests for substances of abuse must complete a training course offered by the manufacturer or provider of the test, an educational facility, or training provided by the Department of Corrections Drug Control Unit with curriculum acceptable to the Health Division. No testing is to be performed prior to the completion of this training. A certificate of satisfactory completion, including the dates and hours of training completed, shall be kept by the SOA testing program manager at

each facility and parole office. A copy shall also be on file with the Drug Control Manager at the Department of Corrections.

(4) Protocols, procedures, and records of all testing shall be maintained as described in this section and shall be followed:

(a) Each local and state correctional facility or parole office shall have a designated substance of abuse program manager who shall assure that:

(A) Written policies established by the Department of Corrections are followed regarding specimen collection, specimen identification, and chain of custody, as defined in OAR 333-024-0310(2);

(B) Written procedure manuals are available to testing individuals, and that the written procedures require following the manufacturer's testing protocol. The written procedures must describe the test limitations and the use of approved standards and quality control, as defined in OAR 333-024-0310(4) and (21).

(C) There is a written record of the:

(i) Date and time the specimen was obtained;

(ii) Date and time the test was performed;

(iii) Lot number of the test kit used, test results, including the results of controls;

(iv) Signature or initials of the analyst.

(b) Quality control procedures as described in this subsection shall be followed:

(A) Each instrument shall be calibrated according to the manufacturer's specifications, with each new lot or shipment of reagents, and after major maintenance;

(B) For manual methods, known positive and negative controls, as defined in OAR 333-024-0310(4), shall be included with each batch of tests or with every ten samples for each analyte of each kit. Known positive and negative controls must be run with each lot

shipment, and at least once per month, if internal procedural controls are included with each test;

(C) For automated instruments, a positive and negative control, as defined in OAR 333-024-0310(4) shall be included at least once per day of use, or following each tenth sample analyzed;

(D) All calibration and control data shall be recorded;

(E) The minimum detectable limit of the analytical method for each substance tested shall be available;

(F) Limits for controls shall be clearly stated and recorded. The corrective action taken when analyses are outside these control limits shall be clearly stated and recorded;

(G) No reagent shall be used beyond its expiration date;

(H) A record shall be kept of each testing individuals' quality control performance. This record will be reviewed by the SOA program manager at least every six months;

(I) Each local and state correctional facility, parole, probation, and post prison program shall be required to participate satisfactorily in a proficiency testing program, as defined in OAR 333-024-0310(16). The proficiency testing programs available from the College of American Pathologists, or the American Association of Bioanalysts, or other proficiency testing program acceptable to the Health Division may be used;

(J) Proficiency testing results and control data shall be reviewed every six months by the SOA program testing manager, and corrective action shall be taken and documented when appropriate. A copy of the report and corrective action must be sent to the Drug Control Manager of the Department of Corrections for review.

(c) If an initial test shows a result indicating the presence of a substance of abuse in the body, a confirmatory test shall be conducted in a licensed clinical laboratory, or a laboratory certified for that testing under the **Clinical Laboratory Improvement Amendments of 1988, Code of Federal Regulations Part 493 -- Laboratory Requirements**, or an equivalent out of state laboratory, if the results are to be used to

deprive or deny any person of any benefit, probation, or parole except as described in ORS 438.435(7).

(d) If any test for substances of abuse is performed outside this state the results of which are used to deprive or deny any person any benefit, the person desiring to use the test shall have the burden to show that the testing procedure used meets or exceeds the testing standards of this state.

Stat. Auth.: ORS 438.050, ORS 438.130, ORS 438.435(4), ORS 438.435(5) & ORS 438.435(6)

Stats. Implemented: ORS 438.435

Hist.: HD 5-1992, f. & cert. ef. 5-15-92; HD 5-1995, f. & cert. ef. 9-13-95; OHD 4-2000, f. & cert. ef. 4-27-00; OHD 9-2000, f. & cert. ef. 11-3-00

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