Chapter 438

1999 EDITION

Clinical and Environmental Laboratories

CLINICAL LABORATORIES

(Generally)

(Clinical Laboratory License)

(Clinical Laboratory Director)

(Inspection and Evaluation)

(Miscellaneous)

CROSS-REFERENCES

Genetic privacy, 659.700 to 659.720

Health Division, 409.310

Worker exposed to infectious disease, procedure, 433.407 to 433.423

Note: The name of the Department of Human Resources has been changed to the Department of Human Services and the title of the Director of Human Resources to the Director of Human Services. The name and title changes become operative on July 1, 2000. See sections 10 and 11, chapter 421, Oregon Laws 1999. References to the department and the director in this chapter use the name and the title that become operative on July 1, 2000.

CLINICAL LABORATORIES

(Generally)

438.010 Definitions for ORS 438.010 to 438.510. As used in ORS 438.010 to 438.510 and 438.990, unless the context requires otherwise:

(1) “Clinical laboratory” or “laboratory” means a facility where the microbiological, serological, chemical, hematological, immunohematological, immunological, toxicological, cytogenetical, exfoliative cytological, histological, pathological or other examinations are performed on materials derived from the human body, for the purpose of diagnosis, prevention of disease or treatment of patients by physicians, dentists and other persons who are authorized by license to diagnose or treat humans.

(2) “Clinical laboratory specialty” or “laboratory specialty” means the examination of materials derived from the human body for the purpose of diagnosis and treatment of patients or assessment of health, employing one of the

following sciences: Serology, microbiology, chemistry, hematology, immunohematology, immunology, toxicology, cytogenetics, exfoliative cytology, histology or pathology.

(3) “Clinician” means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician assistant licensed by the Board of Medical Examiners for the State of Oregon.

(4) “Custody chain” means the handling of specimens in a way that supports legal testimony to prove that the sample integrity and identification of the sample have not been violated, as well as the documentation describing those procedures from specimen collection to the final report.

(5) “Dentist” means a person licensed to practice dentistry by the Oregon Board of Dentistry.

(6) “Director of clinical laboratory” or “director” means the person who plans, organizes, directs and participates in any or all of the technical operations of a clinical laboratory, including but not limited to reviewing laboratory procedures and their results, training and supervising laboratory personnel, and evaluating the technical competency of such personnel.

(7) “Division” means the Health Division of the Department of Human Services.

(8) “Health screen testing” means tests performed for the purpose of identifying health risks, providing health information and referring the person being tested to medical care.

(9) “High complexity laboratory” means a facility that performs testing classified as highly complex in the specialties of microbiology, chemistry, hematology, diagnostic immunology, immunohematology, clinical cytogenetics, cytology, histopathology, oral pathology, pathology, radiobioassay and histocompatibility and that may also perform moderate complexity tests and waived tests.

(10) “High complexity test” means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, chemistry, hematology, immunohematology, diagnostic immunology, clinical cytogenetics, cytology, histopathology, oral pathology, pathology, radiobioassay and histocompatibility as established by the division.

(11) “Laboratory evaluation system” means a system of testing clinical laboratory methods, procedures and proficiency by periodic performance and reporting on test specimens submitted for examination.

(12) “Moderate complexity laboratory” means a facility that performs testing classified as moderately complex in the specialties of microbiology, hematology, chemistry, immunohematology or diagnostic immunology and may also perform any waived test.

(13) “Moderate complexity test” means a procedure performed on materials derived from the human body that meet the criteria for this category of testing in the specialties of microbiology, hematology, chemistry, immunohematology or diagnostic immunology as established by the division.

(14) “Operator of a substances 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 of a substances of abuse on-site screening facility.

(15) “Owner of a clinical laboratory” means the person who owns the clinical laboratory, or a county or municipality operating a clinical laboratory or the owner of any institution operating a clinical laboratory.

(16) “Physician” means a person licensed to practice medicine by the Board of Medical Examiners for the State of Oregon.

(17) “Physician performed microscopy procedure” means a test personally performed by a physician or other clinician during a patient's visit on a specimen obtained during the examination of the patient.

(18) “Physician performed microscopy procedures” means a limited group of tests that are performed only by a physician or clinician.

(19) “Specimen” means materials derived from a human being or body.

(20) “Substances of abuse” 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.

(21) “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.

(22) “Substances of abuse on-site screening test” or “on-site test” means a substances of abuse test that is easily portable and can meet the requirements of the federal 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.

(23) “Waived test” means a procedure performed on materials derived from the human body that meet the criteria

for this category of testing as established by the division. [1969 c.685 s.2; 1989 c.776 s.1; 1993 c.109 s.3; 1997 c.355 s.1; 1999 c.739 s.1]

438.030 Policy. It shall be the declarative purpose of ORS 438.010 to 438.510 and 438.990 to insure the quality of medical laboratory work in order to protect the health and welfare of the people of the State of Oregon by establishing a regulatory program for clinical laboratories. [1969 c.685 s.1]

438.040 Laboratory license required; director to be qualified; permit required of out-of-state laboratory. On and after July 1, 1970, it shall be unlawful:

(1) For any owner or director of a clinical laboratory to operate or maintain a clinical laboratory without a license issued under ORS 438.110 or without a temporary permit issued under ORS 438.150 or to perform or permit the performance of any laboratory specialty for which the laboratory is not licensed except as specified under ORS 438.050, unless the laboratory has been issued a valid certificate from the federal government under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a).

(2) For an out-of-state laboratory to perform health screen testing in Oregon without a permit issued under ORS 438.150 (5).

(3) For any person to serve in the capacity of director of a clinical laboratory without being qualified as a clinical laboratory director under ORS 438.210. [1969 c.685 s.3; 1999 c.341 s.1]

438.050 Application; exceptions. (1) ORS 438.010 to 438.510 and 438.990 apply to all clinical laboratories and laboratory personnel within the State of Oregon, except:

(a) Clinical laboratories operated by the United States Government.

(b) Clinical laboratories operated and maintained purely for research or teaching purposes, and that involve no patient or public health services.

(2) Nothing in ORS 438.010 to 438.510 and 438.990 is intended to confer on any licensed practitioner of the healing arts any authority the practitioner would not otherwise possess under the license. [1969 c.685 ss.4,20; 1973 c.829 s.54; 1979 c.193 s.1; 1993 c.109 s.4]

438.055 Exemption. Clinical laboratories operated by physicians or clinicians that conduct only waived tests and physician performed microscopy procedures used exclusively for the diagnosis and treatment of their patients shall not be subject to regulation that is more strict than regulation imposed under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578; 42 U.S.C. 201 and 263a). [1993 c.109 s.12; 1999 c.341 s.2]

438.060 When permit required for health screen testing; exception. Notwithstanding ORS 438.050, any person performing health screen testing must obtain a permit under ORS 438.150 (5). However, an employer providing health screen testing to employees of the employer is exempt from the applications of ORS 438.010, 438.130, 438.150 and this section if such employer contracts for the testing through a licensed physician, a clinical laboratory or a hospital, which is a permittee of the Health Division as provided in this section. [1989 c.776 s.3]

438.070 Personnel. The Health Division shall establish by rule the qualifications and responsibilities of technical and clinical consultants, general and technical supervisors and testing personnel. A person is qualified to act as a technical or clinical consultant, a general or technical supervisor, or a testing person in a clinical laboratory if the person meets the requirements established by the division. Rules adopted under this section shall not be more stringent than comparable rules adopted under the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578; 42 U.S.C. 201 and 263a). [1993 c.109 s.2]

(Clinical Laboratory License)

438.110 Standards for issuance and renewal of laboratory license. (1) The Health Division shall establish four levels of laboratory licenses as follows:

(a) A high complexity laboratory license;

(b) A moderate complexity laboratory license;

(c) A physician performed microscopy laboratory license; and

(d) A waived laboratory license.

(2) The division shall issue and renew licenses required under ORS 438.040 for any or all clinical laboratory specialties to the owners of clinical laboratories who demonstrate to the satisfaction of the division that:

(a) The clinical laboratory is in compliance with ORS 438.010 to 438.510 and 438.990 and the rules of the division adopted under ORS 438.450;

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

(c) The clinical laboratory has facilities for retaining and does retain complete laboratory records for an appropriate length of time as the division by rule may require; and

(d) The clinical 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 insure protection of the public health. [1969 c.685 s.5; 1971 c.650 s.18; 1993 c.109 s.5; 1999 c.341 s.3]

438.120 Standards for licensing specialties; exceptions. (1) In determining the specialties that are authorized to be performed in a clinical laboratory, the Health Division shall consider laboratory personnel, with particular emphasis on the qualifications of the director, laboratory equipment and any other relevant factors affecting the ability of the laboratory to perform different laboratory specialties.

(2) No laboratory shall be licensed to perform examinations in the fields of surgical pathology, autopsy pathology, exfoliative cytology, or immunohematology, except as the Health Division may establish exemptions from the requirements of this subsection in the field of immunohematology, unless its director is a physician or dentist specifically qualified in these fields.

(3) The list of waived tests, physician performed microscopy procedures and moderate and high complexity tests shall be established by the division. [1969 c.685 s.6; 1993 c.109 s.6; 1999 c.341 s.4]

438.130 License application; fees; expiration and renewal. (1) The application for a license for a clinical laboratory shall be made on forms provided by the Health Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the 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 clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested and such other information as the Health Division may require.

(2)(a) The application shall be accompanied by an annual or biennial license fee to be established by the division. The fee shall be based on test volume, test complexity, the number of specialties performed and private laboratory accreditation. For each level of laboratory testing, the fee shall be not more than 100 percent of the corresponding fee charged by the federal laboratory certification program known as the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a) in effect on July 1, 1999. The fee for substance of abuse screening laboratories not certified under the Clinical Laboratory Improvement Amendments of 1988 shall be comparable to the clinical laboratory fee established under this section.

(b) The division may establish prorated fees for licenses issued for a year or less and when there is a change in the laboratory's owner, director or address. A prorated license fee shall be issued to a laboratory accredited by an organization recognized by the division.

(3) 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.

(4) Subject to prior approval of the Oregon Department of Administrative Services and a report to the Emergency Board prior to adopting the fees and charges, the fees and charges established under this section shall not exceed the cost of administering the regulatory program of the division pertaining to the purpose for which the fee or charge is established, as authorized by the Legislative Assembly within the division's budget, as the budget may be modified by the Emergency Board. [1969 c.685 s.7; 1977 c.284 s.3; 1979 c.696 s.2; 1989 c.776 s.5; 1991 c.703 s.6; 1993 c.109 s.7; 1999 c.341 ss.5,6]

Note: The amendments to 438.130 by section 6, chapter 341, Oregon Laws 1999, become operative July 1, 2000. See section 7, chapter 341, Oregon Laws 1999. The text that is operative until July 1, 2000, including amendments by section 5, chapter 341, Oregon Laws 1999, is set forth for the user's convenience.

438.130. (1) The application for a license for a clinical laboratory shall be made on forms provided by the Health Division and shall be executed by the owner or one of the owners or by an officer of the firm or corporation owning the clinical laboratory, or in the case of a county or municipality, by the public official responsible for operation of the

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 clinical laboratory, the location and physical description of the clinical laboratory, the laboratory specialties for which a license is requested and such other information as the Health Division may require.

(2)(a) The application shall be accompanied by an annual or biennial license fee to be established by the division. The fee shall be based on test volume, test complexity, the number of specialties performed and private laboratory accreditation. For each level of laboratory testing, the fee shall be not more than 95 percent of the corresponding fee charged by the federal laboratory certification program known as the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578, 42 U.S.C. 201 and 263a) in effect on July 1, 1999. The fee for substance of abuse screening laboratories not certified under the Clinical Laboratory Improvement Amendments of 1988 shall be comparable to the clinical laboratory fee established under this section.

(b) The division may establish prorated fees for licenses issued for a year or less and when there is a change in the laboratory's owner, director or address. A prorated license fee shall be issued to a laboratory accredited by an organization recognized by the division.

(3) 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.

(4) Subject to prior approval of the Oregon Department of Administrative Services and a report to the Emergency Board prior to adopting the fees and charges, the fees and charges established under this section shall not exceed the cost of administering the regulatory program of the division pertaining to the purpose for which the fee or charge is established, as authorized by the Legislative Assembly within the division's budget, as the budget may be modified by the Emergency Board.

438.140 License content; display; nontransferability; voidability; special permit when director changes. (1) A license issued to the owner of a clinical laboratory shall show on its face the names of the owners and directors, the location of the laboratory and the clinical laboratory specialties authorized under the license. The license shall be displayed at all times in a prominent place in the laboratory.

(2) A license issued to the owner of a clinical laboratory is not transferable. The license of the laboratory is voided 30 days after a change in 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 case of death of a director, immediate notification to the Assistant Director for Health or a designee who shall be empowered to issue a special temporary permit of 30 days' duration issued to a designated substitute director is required. If a license is voided or a special temporary permit is issued under this section, a new license application, accompanied by the nonrefundable license fee prescribed in ORS 438.130, shall be filed with the Health Division. [1969 c.685 s.8]

438.150 Temporary permit; health screen testing permit; conditions and limitations. (1) In addition to the license of a clinical laboratory required by ORS 438.040, the Health Division may issue a temporary permit valid for a period, to be determined by the Health Division, from the date of issuance in any or all clinical laboratory specialties upon payment of the respective required fees as described in ORS 438.130 (2).

(2) In issuing the temporary permit, the Health Division may require that:

(a) Plans for compliance with applicable laws and rules be submitted with the application for the temporary permit; and

(b) During the period in which the temporary permit is in effect periodic reports be submitted on the progress of the plans for compliance; and

(c) Special temporary provisions specified by the Health Division upon application of the temporary permit be maintained for the protection of the public.

(3) If at any time the Health Division determines that the clinical laboratory can no longer operate in a manner which protects the public health and safety or that the requirements imposed under subsection (2) of this section are not being maintained, the Health Division shall cancel the temporary permit.

(4) One renewal of the temporary permit may be granted if deemed to be in the best interest of public health by the Health Division. The fee for renewal is the respective required fee as described in ORS 438.130 (2).

(5) The Health Division may issue permits for health screen testing.

(6) The Health Division by rule shall specify:

(a) Appropriate quality assurance procedures;

(b) Personnel qualifications;

(c) Standards for counseling and referral of persons being tested;
(d) Tests a health testing service may conduct;
(e) The procedure for applying for a permit; and
(f) The procedure for reporting to the division the location of all health screening facilities.
(7) The Health Division by rule may specify the maximum length of time a health screen testing service may remain in one location. [1969 c.685 s.9; 1989 c.776 s.2]

438.160 Refusal to issue or renew license; suspension or revocation of license or permit. Subject to ORS 183.310 to 183.550, the Health Division may refuse to issue or renew the license, or may suspend or revoke the license or health screen testing permit, of a clinical laboratory if it finds that the owner or director has:
(1) Intentionally made false statements on an application for a clinical laboratory license or any other documents required by the Health Division, or made any misrepresentation in seeking to obtain or retain a license.
(2) Demonstrated incompetence as defined pursuant to regulations promulgated after public hearing.
(3) Intentionally falsified any report.
(4) Referred a specimen for examination to a nonlicensed or an unlicensed clinical laboratory in this state unless the laboratory is exempt from the application of ORS 438.010 to 438.510 and 438.990.
(5) Misrepresented the scope of laboratory service offered by the clinical laboratory or the clinical laboratory specialties authorized by the license.
(6) Rendered a report on clinical laboratory work actually performed in another clinical laboratory without designating the name and address of the clinical laboratory in which the test was performed.
(7) Knowingly had professional connection with or permitted the use of the name of the licensed clinical laboratory or its director by a clinical laboratory that is required to but has not obtained a license.
(8) Failed to perform or cause to be performed within the time specified analysis of test samples as authorized by ORS 438.320, or failed to report on the results of such analysis within the specified time.
(9) Failed to permit within a reasonable time the entry or inspection authorized by ORS 438.310.
(10) Failed to continue to meet requirements of ORS 438.110 and 438.120.
(11) Violated any provision of ORS 438.010 to 438.510 and 438.990. [1969 c.685 s.10; 1993 c.109 s.13; 1999 c.341 s.8]

(Clinical Laboratory Director)

438.210 Qualifications of a laboratory director. A person is qualified to act as a laboratory director of a clinical laboratory if:
(1) The person is a pathologist certified in clinical or anatomical pathology by a national organization or organizations recognized by the Health Division, or is a physician who possesses qualifications equivalent to those required for such certification;
(2) The person is a physician who possesses special qualifications that enable the person to perform as a laboratory director, or is directing a laboratory on January 1, 1970;
(3) The person has an earned degree of Doctor of Science or Doctor of Philosophy, or an acceptable degree as determined by the Health Division, from an accredited college or university, with a major in the chemical, physical, or biological sciences and possesses special qualifications as described in the administrative rules of the Health Division that enable the person to perform as a laboratory director;
(4) The person is the member of a group of five or more physicians who operate on November 4, 1993, a laboratory performing work only on their patients and who is designated by the group to be the director; or
(5) The person was responsible for the direction of a clinical laboratory for at least 12 months within the five years preceding January 1, 1970, and has had at least two years of pertinent clinical laboratory experience, as determined by the Health Division. [1969 c.685 s.12; 1993 c.109 s.8]

438.220 Special qualifications for laboratory director at chiropractic college. Notwithstanding ORS 438.210, a person is qualified to act as the laboratory director of the clinical laboratory at any accredited chiropractic college in this state for the benefit of chiropractic patients if that person is a chiropractic physician licensed by the State Board of Chiropractic Examiners, and possesses special qualifications, as determined by the State Board of Chiropractic Examiners, that enable that person to perform as a laboratory director. [1979 c.303 s.2]

(Inspection and Evaluation)

438.310 Inspection of laboratory premises; owner to submit reports and findings on communicable disease; information confidential. (1) The Health Division or its authorized representative may:

(a) At reasonable times enter the premises of a clinical laboratory licensed or subject to being licensed under ORS 438.010 to 438.510 and 438.990 to inspect the facilities, methods, procedures, materials, staff, equipment, laboratory results and records of the clinical laboratory.

(b) Require the owner or director to submit reports on the operations and procedures of the laboratory.

(c) Require the owner or director to submit initial laboratory findings indicative of communicable disease as defined by law or by rule. Each report shall include the name of the person from whom the specimen was obtained, if the name was reported to the laboratory, and the name and address of the physician for whom such examination or test was made. Such reports shall not be construed as constituting a diagnosis nor shall any laboratory making such report be held liable under the laws of this state for having violated a trust or confidential relationship.

(2) The Assistant Director for Health or a designee, the division, or any employee thereof, shall not disclose information contained in reports on communicable diseases submitted to the division under subsection (1) of this section except as such information is made available to employees of the division and to local health officers for purposes of administering the public health laws of this state. However, information contained in such reports may be used in compiling statistical and other data in which persons are not identified by name or otherwise.

(3) The division shall by rule set standards for the recognition of private laboratory accrediting organizations whose standards meet or exceed federal standards. A laboratory that is accredited by a private laboratory accrediting organization recognized by the Health Division under this section may submit proof of such accreditation to the Health Division. Upon receipt of such proof, the Health Division shall issue a license pursuant to ORS 438.130. [1969 c.685 s.13; 1993 c.109 s.9]

438.320 Laboratory evaluation system; quality control systems. (1) The Health Division shall institute a laboratory evaluation system, as defined in ORS 438.010, and shall make such rules as are necessary to insure quality control of laboratory work.

(2) As part of this system, the division may require each laboratory to:

(a) Participate in on-site inspection and testing;

(b) Analyze test samples submitted by the division prior to, during or subsequent to the inspection; and

(c) Contract with, at the laboratory's own expense, a division-approved source of test samples for such test samples to be submitted periodically to the laboratory and to be returned to that source for grading after testing. The test results shall be made available to the division.

(3) The procedures under subsection (2) of this section shall be referred to as external quality control. The samples are to be tested by regularly assigned personnel using routine methods. The test samples shall be confined to the specialty of the laboratory as indicated on the license. A specified time shall be allowed for such testing and reporting of the results and shall be the time required under conditions of normal operation.

(4) In addition to external quality control, each clinical laboratory shall establish an internal laboratory quality control system pursuant to rules of the division including but not necessarily limited to the testing of reference or control sera and other biological samples, verifying concurrent calibration standards and control charts recordings, and reporting on its control system as required by the division. [1969 c.685 s.14; 1983 c.740 s.154; 1993 c.109 s.10]

438.410 [Formerly 433.310; repealed by 1971 c.650 s.51]

(Miscellaneous)

438.420 Communicable disease reports to be from licensed laboratory. When the control or release of a case contact or carrier of a communicable disease is dependent on laboratory findings, the health officer may require such findings to be obtained by a clinical laboratory licensed by the Health Division. [Formerly 433.325]

438.430 Specimens taken from and reports made only to persons authorized to use results. (1) Except as otherwise provided in ORS 438.010 to 438.510 and 438.990, a clinical laboratory shall examine specimens only at the request of a physician, dentist, or other person authorized by law to use the findings of laboratory examinations.

(2) No person shall report the result of any test, examination, or analysis of a specimen submitted for evidence of

human disease except to a physician, dentist, their agents, or other person authorized by law to employ the results thereof in the conduct of a practice or in the fulfillment of official duties. Reports shall not be issued to the patient concerned except with the consent of the physician or other authorized person. [1969 c.685 s.21]

438.435 Testing for substance abuse. (1) In addition to duties which a clinical laboratory may perform under ORS 438.010 to 438.510 and 438.990, a laboratory is authorized to perform appropriate tests, examinations or analyses on materials derived from the human body for the purpose of detecting substances of abuse in the body. All laboratories performing the tests, examinations or analyses must be licensed under the provisions of ORS 438.010 to 438.510 and 438.990 and must employ qualified technical personnel to perform the tests, examinations and analyses.

(2) In order to perform such tests, examinations or analyses, the laboratory may examine specimens submitted by persons other than those described in ORS 438.430 (1) and shall report the result of any test, examination or analysis to the person who submitted the specimen. When the substance of abuse test is for nonmedical employment or pre-employment purposes, and a written request is provided, the test result shall be reported to the person from whom the specimen was originally obtained.

(3) When the specimen of a person tested for substances of abuse is submitted to the laboratory and the test result is positive, the laboratory shall perform a confirming test which has been designated by rule of the Health Division as the best available technology for use to determine whether or not the substance of abuse identified by the first test is present in the specimen prior to reporting the test results.

(4) The Health Division by rule shall set standards for special category laboratories that engage only in the initial testing for substances of abuse in the body, including registration procedures for such laboratories and personnel.

(5) The operator of a substances of abuse on-site screening facility may use substances of abuse on-site screening tests if the test results are not for use in diagnosing or preventing disease and are not for use by physicians, dentists or other licensed health care professionals in treating humans. Any entity using the test shall pay a yearly filing fee, not to exceed $50, and file a registration form as provided by rule of the Health Division of the Department of Human Services that:

(a) States the current name and address of the entity, the telephone number of the entity, if any, and the name of a contact individual at each on-site facility operated by the entity; and

(b) Certifies that:

(A) The tests are being administered according to the federal Food and Drug Administration package insert that accompanies the test;

(B) The tests are being administered according to the instructions of the manufacturer;

(C) Custody chain procedures are being followed;

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

(E) If the substances of abuse on-site screening facility obtains a positive test 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 and 438.150 or an equivalent out-of-state facility and the presence of a substance of abuse confirmed prior to release of the on-site test result.

(6) The Health Division by rule shall set reasonable standards for the screening by correctional agencies of inmates within state and local correctional facilities and offenders on parole, probation or post-prison supervision for substances of abuse. The standards shall include, but not be limited to, the establishment of written procedures and protocols, the qualifications and training of individuals who perform screening tests, the approval of specific technologies and the minimum requirements for record keeping, quality control and confirmation of positive screening results.

(7) If an initial test by a special category laboratory under subsection (4) of this section or a special category screening under subsection (6) of this section 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 if the results are to be used to deprive or deny any person of any employment or benefit. If a screening test of an inmate of a state or local correctional facility is positive for a substance of abuse, the inmate may be held in a secure facility pending the outcome of the confirmatory test. If the confirmatory test is positive, the inmate may be held in a secure facility pending the outcome of any hearing to determine what action will be taken.

(8) If any test for substances of abuse is performed outside this state the results of which are to be used to deprive or deny any person any employment or 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. [1987 c.669 s.2; 1991 c.808 s.1; 1997 c.355 s.2; 1999 c.739 s.2]

438.440 Disposition of fees. All moneys received by the Health Division under ORS 438.010 to 438.510 and 438.990 shall be credited to the Health Division Account and shall be used for payment of the expenses of the Health Division in administering the provisions of ORS 438.010 to 438.510 and 438.990. [1969 c.685 s.16]

438.450 Rules. The Health Division shall make such rules as are necessary for carrying out ORS 438.010 to 438.510 and 438.990 in accordance with ORS 183.330. [Formerly 433.335]

438.510 Prohibited acts. It is unlawful for the owner of a clinical laboratory or the director of a clinical laboratory to:

(1) Operate or maintain a clinical laboratory unless the laboratory is under personal supervision of a director who is qualified to supervise the laboratory.

(2) Violate any provision of ORS 438.010 to 438.510 and 438.990. [1969 c.685 s.11; 1987 c.669 s.3]

ENVIRONMENTAL LABORATORIES

438.605 Definitions for ORS 438.605 to 438.620. As used in ORS 438.605 to 438.620, 448.280 and 448.285:

(1) “Accrediting authority” means the official accrediting authority for the Oregon environmental laboratory accreditation program comprised of the Assistant Director for Health or designee, the Director of the Department of Environmental Quality or designee and the Director of Agriculture or designee.

(2) “Division” means the Health Division of the Department of Human Services.

(3) “Environmental laboratory” means a fixed location or mobile facility that performs chemical, physical, radiological, microbiological or biological testing of environmental samples or the collection of environmental samples.

(4) “Environmental testing” means laboratory analysis of any matter, pollutant, contaminant or hazardous substance subject to regulation pursuant to:

(a) Rules adopted or enforced by the Health Division, the Department of Environmental Quality or the State Department of Agriculture; or

(b) A federal environmental statute or regulation administered or enforced by the United States Environmental Protection Agency. [1999 c.1063 s.1]

438.610 Standards for accreditation. (1) The Health Division, in concurrence with the accrediting authority, may adopt by rule standards for any laboratory seeking accreditation and performing environmental testing for a fee or for determining compliance with environmental statutes, rules or regulations.

(2) In developing standards under subsection (1) of this section, the Health Division shall cooperate with and may seek advice from the United States Environmental Protection Agency and any other state or federal agency that may have adopted rules or regulations for environmental monitoring.

(3) The standards adopted under this section may address testing and sampling procedures or methods, record keeping, disposal or retention of testing materials or samples, or any other practice related to work performed by an environmental laboratory. [1999 c.1063 s.2]

438.615 Environmental laboratory accreditation program. The Health Division, in concurrence with the accrediting authority, shall establish by rule and implement an environmental laboratory accreditation program. The standards for accreditation may be equivalent to, but may not exceed, standards adopted by national accreditation programs. [1999 c.1063 s.3]

438.620 Accreditation fees; disposition of fees. (1) In conjunction with the environmental laboratory accreditation program established under ORS 438.615, the Health Division may establish and collect a fee for laboratory accreditation under the program. A fee imposed under this section shall not exceed the cost of administering the program.

(2) Prior to imposing the fee under subsection (1) of this section, the Health Division shall obtain the approval of the Oregon Department of Administrative Services and report to the appropriate legislative committee.

(3) All moneys collected by the Health Division under this section shall be deposited in a dedicated account of the Health Division. Such moneys are continuously appropriated to the division to pay the costs of the division, the State Department of Agriculture and the Department of Environmental Quality in administering the environmental laboratory accreditation program established under ORS 438.615. [1999 c.1063 s.4]

PENALTIES

438.990 Penalties. Violation of any provision of ORS 438.040 or 438.510 is a Class A misdemeanor. Each day of continuing violation shall be considered a separate offense. [1969 c.685 s.22; 1977 c.582 s.45]

CHAPTER 439

[Reserved for expansion]