Chapter 438

2017 EDITION

Laboratories; Anatomical Material

CLINICAL LABORATORIES

(Generally)

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

(1) "Authority" means the Oregon Health Authority.

(2) "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.

(3) "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.

(4) "Clinician" means a nurse practitioner licensed and certified by the Oregon State Board of Nursing, or a physician assistant licensed by the Oregon Medical Board.

(5) "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.

(6) "Dentist" means a person licensed to practice dentistry by the Oregon Board of Dentistry.

(7) "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.

(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 authority.

(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 authority.

(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 Oregon Medical Board.

(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, cannabis and controlled substances.

(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 authority. [1969 c.685 §2; 1989 c.776 §1; 1993 c.109 §3; 1997 c.355 §1; 1999 c.739 §1; 2001 c.104 §168; 2001 c.900 §255; 2009 c.595 §698; 2017 c.21 §62]

438.030 Policy. It shall be the declarative purpose of ORS 438.010 to 438.510 to ensure 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 §1; 2001 c.104 §169]

438.040 Laboratory license; out-of-state laboratory permit; qualifications of director. It is 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 §3; 1999 c.341 §1; 2005 c.22 §298]

438.050 Application; exceptions. (1) ORS 438.010 to 438.510 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 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 §§4,20; 1973 c.829 §54; 1979 c.193 §1; 1993 c.109 §4; 2001 c.104 §170]

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 §12; 1999 c.341 §2]

438.060 Permit 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 Oregon Health Authority as provided in this section. [1989 c.776 §3; 2009 c.595 §699]

438.070 Personnel; rules. The Oregon Health Authority 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 authority. 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 §2; 2009 c.595 §700]

(Clinical Laboratory License)

438.110 Standards for issuance and renewal of laboratory license. (1) The Oregon Health Authority 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 authority 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 authority that:

(a) The clinical laboratory is in compliance with ORS 438.010 to 438.510 and the rules of the authority 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 authority by rule may require; and

(d) The clinical laboratory meets the standards of the authority 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 §5; 1971 c.650 §18; 1993 c.109 §5; 1999 c.341 §3; 2001 c.104 §171; 2009 c.595 §701]

438.120 Standards for licensing specialties; exceptions. (1) In determining the specialties that are authorized to be performed in a clinical laboratory, the Oregon Health Authority 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, unless its director is a physician or dentist specifically qualified in these fields. The authority may establish exemptions from the requirements of this subsection for the field of immunohematology.

(3) The list of waived tests, physician performed microscopy procedures and moderate and high complexity tests shall be established by the authority. [1969 c.685 §6; 1993 c.109 §6; 1999 c.341 §4; 2009 c.595 §702]

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 Oregon Health Authority 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 authority may require.

(2)(a) The application shall be accompanied by an annual or biennial license fee to be established by the authority. 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 authority 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 authority.

(3) Unless sooner voided, suspended or revoked, all licenses issued under this section expire on June 30 of the one-year or two-year cycle following the date of issuance or on such date as may be specified by authority rule. Licenses issued under this section shall be renewable in the manner prescribed by the authority.

(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 authority pertaining to the purpose for which the fee or charge is established, as authorized by the Legislative Assembly within the authority's budget, as the budget may be modified by the Emergency Board. [1969 c.685 §7; 1977 c.284 §3; 1979 c.696 §2; 1989 c.776 §5; 1991 c.703 §6; 1993 c.109 §7; 1999 c.341 §§5,6; 2007 c.768 §4; 2009 c.595 §703]

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 Director of the Oregon Health Authority 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 authority. [1969 c.685 §8; 2009 c.595 §704]

438.150 Temporary permit; fees; health screen testing permit; conditions and limitations; rules. (1) In addition to the license of a clinical laboratory required by ORS 438.040, the Oregon Health Authority may issue a temporary permit valid for a period, to be determined by the authority, 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 authority may require that:

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

(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 authority upon application of the temporary permit be maintained for the protection of the public.

(3) If at any time the authority determines that the clinical laboratory can no longer operate in a manner that protects the public health and safety or that the requirements imposed under subsection (2) of this section are not being maintained, the authority 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 authority. The fee for renewal is the respective required fee as described in ORS 438.130 (2).

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

(6) The authority 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 authority the location of all health screening facilities.

(7) The authority by rule may specify the maximum length of time a health screen testing service may remain in one location. [1969 c.685 §9; 1989 c.776 §2; 2007 c.71 §122; 2009 c.595 §705]

438.160 Refusal to issue or renew license; suspension or revocation of license or permit. Subject to ORS chapter 183, the Oregon Health Authority 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 authority, 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.

(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. [1969 c.685 §10; 1993 c.109 §13; 1999 c.341 §8; 2001 c.104 §172; 2009 c.595 §706]

(Clinical Laboratory Director)

438.210 Qualifications of 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 Oregon Health Authority, 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 authority, 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 authority that enable the person to perform as a laboratory director;

(4) The person is a member of a group of five or more physicians who operate on November 4, 1993, a laboratory performing work only on their patients and is the member 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 authority. [1969 c.685 §12; 1993 c.109 §8; 2007 c.71 §123; 2009 c.595 §707]

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 §2]

(Inspection and Evaluation)

438.310 Inspection of laboratory premises; owner to submit reports and findings on communicable disease; information confidential. (1) The Oregon Health Authority 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 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 Director of the Oregon Health Authority or a designee, the authority, or any employee thereof, shall not disclose information contained in reports on communicable diseases submitted to the authority under subsection (1) of this section except as such information is made available to employees of the authority 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 authority 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 authority under this section may submit proof of such accreditation to the authority. Upon receipt of such proof, the authority shall issue a license pursuant to ORS 438.130. [1969 c.685 §13; 1993 c.109 §9; 2001 c.104 §173; 2009 c.595 §708]

438.320 Laboratory evaluation system; rules; quality control systems. (1) The Oregon Health Authority 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 authority may require each laboratory to:

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

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

(c) Contract with, at the laboratory's own expense, an authority-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 authority.

(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 authority 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 authority. [1969 c.685 §14; 1983 c.740 §154; 1993 c.109 §10; 2009 c.595 §709]

438.410 [Formerly 433.310; repealed by 1971 c.650 §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 Oregon Health Authority. [Formerly 433.325; 2009 c.595 §710]

438.430 Examination, specimens; reports and results. (1) Except as otherwise provided in ORS 438.010 to 438.510, 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) A person may not report the result of any test, examination, or analysis of a specimen submitted for evidence of human disease except to:

(a) The patient; and

(b) 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.

(3) A clinical laboratory shall provide the results of a test, examination or analysis of a specimen submitted by a patient in writing to the patient:

(a) Not sooner than seven days after receiving a request for the results from the patient; or

(b) Immediately upon receiving authorization from the doctor, dentist or other person who requested the test, examination or analysis to provide the results to the patient. [1969 c.685 §21; 2001 c.104 §174; 2003 c.376 §1; 2009 c.583 §1]

438.435 Testing for substance of abuse; rules; fees. (1) In addition to duties which a clinical laboratory may perform under ORS 438.010 to 438.510, 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 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 preemployment 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 Oregon Health Authority 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 authority 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 authority 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 authority 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 §2; 1991 c.808 §1; 1997 c.355 §2; 1999 c.739 §2; 2001 c.104 §175; 2009 c.595 §711]

438.440 Disposition of fees. All moneys received by the Oregon Health Authority under ORS 438.010 to 438.510 and 438.990 shall be credited to the Public Health Account and shall be used for payment of the expenses of the authority in administering the provisions of ORS 438.010 to 438.510 and 438.990. [1969 c.685 §16; 2009 c.595 §712]

438.450 Rules. The Oregon Health Authority shall make such rules as are necessary for carrying out ORS 438.010 to 438.510 in accordance with ORS 183.330. [Formerly 433.335; 2001 c.104 §176; 2009 c.595 §713]

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. [1969 c.685 §11; 1987 c.669 §3; 2001 c.104 §177]

ENVIRONMENTAL LABORATORIES

438.605 Definitions for ORS 438.605 to 438.620, 448.280 and 448.285. 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 Director of the Oregon Health Authority or designee, the Director of the Department of Environmental Quality or designee and the Director of Agriculture or designee.

(2) "Authority" means the Oregon Health Authority.

(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 Oregon Health Authority, 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 §1; 2009 c.595 §714]

438.610 Standards for accreditation; rules. (1) The Oregon Health Authority, 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 authority 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 §2; 2009 c.595 §715]

438.615 Environmental laboratory accreditation program; rules. The Oregon Health Authority, 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 §3; 2009 c.595 §716]

438.620 Accreditation fees; disposition of fees. (1) In conjunction with the environmental laboratory accreditation program established under ORS 438.615, the Oregon Health Authority 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 authority shall obtain the approval of the Oregon Department of Administrative Services and report to the appropriate legislative committee.

(3) All moneys collected by the Oregon Health Authority under this section shall be deposited in a dedicated account of the authority. Such moneys are continuously appropriated to the Oregon Health Authority to pay the costs of the authority, 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 §4; 2009 c.595 §717]

ANATOMICAL MATERIAL

438.705 Definitions for ORS 438.705 to 438.720 and 438.994. As used in ORS 438.705 to 438.720 and 438.994:

(1) "Anatomical material" means the body of a dead human or a cell, group of cells or body part taken from the body of a dead human.

(2) "Donor" has the meaning given that term in ORS 97.953.

(3)(a) "Nontransplant anatomical research recovery organization" means a person that engages in the recovery or distribution of anatomical material from a donor for research or education purposes other than transplanting the anatomical material or therapy.

(b) "Nontransplant anatomical research recovery organization" does not include:

(A) A hospital or other health care facility, as those terms are defined in ORS 442.015;

(B) A public corporation, as defined in ORS 353.010;

(C) A public or private institution of higher education; or

(D) A clinical laboratory, as defined in ORS 438.010, that is:

(i) Licensed under ORS 438.010 to 438.510; and

(ii) Owned or controlled by, or under common ownership with, a hospital described in subparagraph (A) of this paragraph. [2013 c.356 §1]

438.710 Licensure of nontransplant anatomical research recovery organizations; rules; fees. (1) A person may not act as a nontransplant anatomical research recovery organization unless the person is licensed as a nontransplant anatomical research recovery organization by the Oregon Health Authority.

(2) The authority shall adopt rules establishing an application process and fees for obtaining and renewing a nontransplant anatomical research recovery organization license. The fee for obtaining or renewing a

license under this subsection may not exceed $1,750.

(3) A license issued or renewed under this section expires two years after the date of issuance or renewal.

(4) The license required by this section is in addition to and not in lieu of any other license required by law.

(5) The authority shall deposit fees collected under this section into the Oregon Health Authority Fund established in ORS 413.101. Moneys deposited in the fund under this subsection are continuously appropriated to the authority for the purposes of carrying out the duties, functions and powers of the authority under ORS 438.705 to 438.720 and 438.994. [2013 c.356 §2]

438.715 Organization operations. (1) A nontransplant anatomical research recovery organization shall maintain a record of each donor from whom the organization obtains anatomical material. The record must include:

(a) Documentation showing that the donor donated the anatomical material for the purpose of research or education;

(b) The name and address of each person that had possession of the anatomical material before the organization took possession of the anatomical material; and

(c) Documentation of the disposition of the anatomical material by the organization, including the name and address of each person that receives anatomical material from the organization.

(2) If a nontransplant anatomical research recovery organization returns any anatomical material to a relative or personal representative of a donor, the organization shall disclose to the relative or personal representative whether all or part of the donor's body is being returned.

(3) A nontransplant anatomical research recovery organization shall dispose of any anatomical material not returned to a relative or personal representative of the donor in accordance with all laws pertaining to the disposition of human remains.

(4) If a nontransplant anatomical research recovery organization accepts an offer from an individual to donate anatomical material to the organization, the organization shall provide to the individual clear notice as to whether or not the organization guarantees the coverage of a cost related to transporting and disposing of the individual's anatomical material, including coverage of costs in instances in which the individual or a relative or personal representative of the individual subsequently rescinds, or the organization later rejects, the offer of anatomical material. [2013 c.356 §3]

438.720 Rules; inspection of organization premises and records. (1) The Oregon Health Authority may:

(a) Adopt rules to implement ORS 438.705 to 438.720 and 438.994;

(b) Inspect the premises and records of a nontransplant anatomical research recovery organization as is reasonably necessary to determine compliance with ORS 438.710 and 438.715; and

(c) In lieu of conducting inspections authorized under paragraph (b) of this subsection, accept accreditation from an accrediting body approved by the authority.

(2) To be approved under subsection (1)(c) of this section, an accrediting body must:

(a) Require a nontransplant anatomical research recovery organization to document processes related to the recovery, handling and distribution of anatomical material and submit to the accrediting body that documentation.

(b) Require a nontransplant anatomical research recovery organization to keep and maintain all records related to the recovery or distribution of anatomical material for at least 10 years.

(c) Conduct, or have a designee conduct, regular on-site compliance inspections of a nontransplant anatomical research recovery organization's records, processes and materials relating to:

(A) Donor intake;

(B) Acquisition, preparation, labeling, packaging, storage and distribution of anatomical material; and

(C) Any inspection of a facility owned or operated by the nontransplant anatomical research recovery organization. [2013 c.356 §4]

PENALTIES

438.990 Penalties for ORS 438.040 and 438.510. 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 §22; 1977 c.582 §45]

438.994 Penalties for ORS 438.710 and 438.715. (1) In accordance with ORS chapter 183, the Oregon Health Authority may:

(a) Impose a civil penalty in an amount not to exceed $1,000 for each violation of ORS 438.710 or 438.715; and

(b) Suspend or revoke a license issued or renewed under ORS 438.710 for a violation of ORS 438.715.

(2) The authority shall deposit penalties collected under this section into the Oregon Health Authority Fund established in ORS 413.101. Moneys deposited in the fund under this subsection are continuously appropriated to the authority for the purposes of carrying out the duties, functions and powers of the authority under ORS 438.705 to 438.720 and 438.994. [2013 c.356 §5]

CHAPTER 439

[Reserved for expansion]