DEPARTMENT OF HEALTH

Repeal of Chapter 11-110, "Clinical Laboratories and Laboratory Personnel"
and the
Adoption of Chapter 11-110.1, "Clinical Laboratories and Laboratory Personnel,"
Hawaii Administrative Rules

Summary

1. Chapter 11-110, Hawaii Administrative Rules, entitled "Clinical Laboratories and Laboratory Personnel," is repealed.

2. Chapter 11-110.1, Hawaii Administrative Rules, entitled "Clinical Laboratories and Laboratory Personnel," is adopted.

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DEPT OF HEALTH

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 110

CLINICAL LABORATORIES AND LABORATORY PERSONNEL

Repealed

§§11-110-1 to 11-100-36 Repealed. [JUL 05 2007]

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 110.1

CLINICAL LABORATORIES AND LABORATORY PERSONNEL

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Historical Note: Chapter 11-110.1 is based substantially upon Chapter 11-110, Hawaii Administrative Rules. [Eff 10/19/02]

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SUBCHAPTER 1

GENERAL PROVISIONS

§11-110.1-1 Purpose. The purpose of this chapter is to protect the health, welfare, and safety of the public by establishing minimum licensure standards for clinical laboratories and clinical laboratory personnel. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13, 321-14, 321-15) (Imp: HRS §§321-11, 321-13, 321-14, 321-15)

§11-110.1-2 Definitions. As used in this chapter:

"Accredited college or university" means a regionally accredited college or university in the United States. This definition includes any foreign institution of higher education that the department determines meets substantially equivalent requirements.

"Accredited program" means a structured training program or curriculum in a college or university accredited by a nationally recognized accrediting agency or an association recognized and accepted by the department.

"Authorized person" means a physician licensed pursuant to HRS Chapter 453, osteopath licensed pursuant to HRS Chapter 460, dentist licensed pursuant to HRS Chapter 448, veterinarian licensed pursuant to HRS Chapter 471, naturopathic physician licensed pursuant to HRS Chapter 455, podiatrist licensed pursuant to HRS Chapter 463E, advanced practice nurse practitioner licensed pursuant to HRS Chapter 457, therapeutically certified optometrist licensed pursuant to HRS Chapter 459, physician assistant licensed pursuant to HRS Chapter 453 under the supervision of a licensed physician, pharmacist licensed pursuant to HRS Chapter 461 in collaboration with a licensed physician, chiropractor licensed pursuant to HRS Chapter 442 to determine referral to an internal medical physician or other health care practitioner for supportive patient care management, or designee of an authorized person, and others deemed qualified by the department to order, receive and interpret laboratory test results within

the scope of their practice. Qualifications shall include successfully completing an accredited training program and passing a certification examination that demonstrates competency in ordering and interpreting laboratory test results.

"Certifying agency acceptable to the department" means a national certifying agency of laboratory personnel that is acceptable to the Secretary of the United States Department of Health and Human Services, including, but not limited to, the American Society of Clinical Pathologists and the National Credentialing Agency for Laboratory Personnel.

"CLIA" means Clinical Laboratory Improvement Amendments of 1988. 42 C.F.R. Part 493 sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens. 42 C.F.R. Part 493 implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act.

"Clinical laboratory" means a facility where the microbiological, serological, chemical, hematological, biophysical, toxicological, cytological, pathological, or other examinations of specimens taken from the human body are performed to obtain information for diagnosis, prophylaxis, or treatment of a disease or assessment of a medical condition.

"Clinical laboratory director" or "laboratory director" means a person who is responsible for the administrative, technical, and scientific operation of a clinical laboratory including the supervision of procedures for testing and the reporting of the test results.

"Clinical laboratory owner" means a person or entity in whom is vested the ownership rights of control, possession, and dominion of a clinical laboratory.

"Clinical laboratory sciences" include clinical chemistry, clinical microbiology, hematology, clinical immunology, immunohematology, cytology, cytogenetics, and histology.

"Collecting depot" means a place separate from patient care facilities and where specimens are received or taken from the body of an individual for laboratory examination elsewhere.

"Department" means the department of health, State of Hawaii.

"Director of health" or "director" means the director of the department of health, State of Hawaii, or the director's designee.

"Foreign certifying agency" means a certifying agency of laboratory personnel educated in a country outside of the United States and its territories.

"Full-time experience" means employment or activity that constitutes at least forty hours a week or its equivalent. For instance, one year of full-time experience is equivalent to two years of half-time experience.

"High complexity tests" means laboratory tests categorized as high complexity pursuant to 42 C.F.R. part 493 subpart A.

"Laboratory acceptable to the department" means a clinical laboratory licensed by the department or licensed by another state whose requirements are equal to or more stringent than the requirements of this chapter, a clinical laboratory certified pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 C.F.R. part 493, a clinical laboratory certified under 21 C.F.R. parts 600-680, or a clinical laboratory acceptable to the U. S. Department of Health and Human Services.

"Laboratory consultant" means a clinical laboratory director or medical technologist licensed under this chapter.

"Laboratory specialty" means clinical chemistry, hematology, immunohematology, microbiology, immunology, cytology, cytogenetics, histocompatibility, molecular biology and other specialties recognized by a certifying agency acceptable to the department.

"Moderate complexity tests" means laboratory tests categorized as moderate complexity pursuant to 42 C.F.R. part 493 subpart A.

"Person" means an individual, firm, association, corporation, partnership, organization, municipality, political subdivision, or any other forms of entity, whether organized for profit or not.

"Pertinent laboratory experience" means experience performing laboratory tests in a clinical laboratory acceptable to the department, and which are appropriately complex for the category of licensure

sought, as determined by the director.

"Point of care test" or "POCT" means a test that is performed using a portable laboratory testing system, analytical instrument, kit or procedure that may be transported to the site of a patient and is classified as a waived or moderate complexity test pursuant to 42 C.F.R. part 493 subpart A.

"Provider-performed microscopy procedures" or "PPMP" means a procedure meeting the specifications described in 42 C.F.R. part 493 subpart A.

"Waived test" means a test system, assay, or examination that the U.S. Department of Health and Human Services has determined meets the CLIA statutory criteria as specified for waiver under section 353(d)(3) of the Public Health Service Act (42 U.S.C. 263a). [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13, 321-14, 321-15) (Imp: HRS §§321-11, 321-13, 321-14, 321-15)

§11-110.1-3 Variances and waivers. The department, upon application, may grant variances and waivers to specific requirements of these rules when the department determines that the intended protections afforded by the rule are being met; and

(1) The rule would impede experimentation or demonstration of new and innovative approaches to delivery of services, where the approach has the potential to improve service delivery; or

(2) Strict application would cause undue hardship and equivalent standards affording protection of health, safety, and care exist and will be met in lieu of the exact rule requirements.

[Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110.1-4 Severability clause. Should any section, paragraph, sentence, clause, phrase, or application of this chapter be declared unconstitutional or invalid for any reason, the remainder of this chapter shall not be affected thereby. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, §11-110.1-5, 321-13)

SUBCHAPTER 2
CLINICAL LABORATORIES

§11-110.1-5 Applicability of subchapter 2 and exemptions. Subchapter 2 applies to all clinical laboratories within the State, except laboratories that are:

(1) Operated by the United States government;
(2) Operated and maintained exclusively for research and teaching purposes, involving no patient services whatsoever;
(3) Certified by CLIA pursuant to 42 C.F.R. part 493 subpart A and operated by a licensed physician at a stated location where clinical laboratory tests are performed exclusively for the physician's own patients. The licensed physician shall serve as the laboratory director for this laboratory. Such clinical laboratories shall comply with section 11-110.1-16(e);
(4) Operated by a police department of any county and perform breath alcohol analysis;
(5) Certified as a clinical laboratory under 42 C.F.R. part 493 subpart A and perform laboratory testing for pulmonary function in a licensed medical facility; or
(6) Conducting any study of public health importance with the written approval of the director. [Eff JUL 05 2007] (Auth: HRS §§321-1, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110.1-6 Requirements for a clinical laboratory permit or license. (a) No person shall establish, conduct, maintain, or operate a clinical laboratory in the State without a valid and effective clinical laboratory permit or license issued by the department.

(b) An application shall be submitted for each address in which clinical laboratory tests are performed.

(c) The following laboratories shall be exempt from the requirements of subsection (b):

(1) Clinical laboratories located within contiguous buildings in a hospital, share the same address, and under the direction of the same laboratory director may apply for a single license or permit.

(2) Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the license or permit of the designated primary site or home base, using the address of the primary site or home base.

(3) Not-for-profit or State or local government laboratories that engage in limited (not more than a combination of fifteen PPMPs, POCTs or waived tests per license or permit) public health testing may file a single application.

(d) All completed applications shall be approved or denied no later than sixty calendar days following the date that the complete application is received.

(e) A clinical laboratory license or permit shall be effective for a period of not more than twenty-four months.

(f) The clinical laboratory director shall display the permit or license issued to the laboratory by the department in a prominent place in the laboratory.

(g) The clinical laboratory director shall notify the department in writing of a change in name, location, director, or owner of the laboratory within thirty days of the actual change. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-7 <u>Requirements for a class I clinical laboratory permit.</u> (a) A person intending to operate a clinical laboratory may apply for a class I permit if the laboratory:

(1) Performs only waived or provider performed microscopy procedures, or both, pursuant to 42 C.F.R. part 493 subpart A, on its premises;

(2) Is certified as a clinical laboratory under 42 C.F.R. part 493 subpart A; and
(3) Remits applicable fees.

(b) A person applying for an initial class I clinical laboratory permit and renewal shall complete application forms provided by the department. The application shall include at a minimum:

(1) Name and address of the clinical laboratory where laboratory testing is performed;
(2) Name and address of the owner of the clinical laboratory;
(3) Name of the laboratory director;
(4) Name of the laboratory consultant if the laboratory director is not a clinical laboratory director or medical technologist licensed by the State; and
(5) List of tests and methodologies and annual test volume to be performed by the laboratory.

(c) The laboratory director of a class I clinical laboratory shall:

(1) Be accessible to the laboratory and provide onsite, telephone, or electronic consultation as needed;
(2) Visit the laboratory at least two times per year;
(3) Approve all laboratory tests performed in the laboratory and have written protocols available for all testing personnel;
(4) Prior to patient testing, provide training to testing personnel and document the personnel's competency to perform tests accurately and reliably;
(5) Ensure specimens for laboratory testing are properly collected;
(6) Ensure control materials meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results;
(7) Ensure patient test results are reported accurately and in a timely manner; and
(8) Ensure all federal, state, and county safety regulations are followed.

(d) The laboratory director of a class I clinical laboratory may delegate the laboratory director's duties in writing to the laboratory's laboratory consultant.

(e) The department may inspect the laboratory for initial approval and renewal of its class I permit. A clinical laboratory with a class I permit shall allow the inspection of its premises, records, materials, equipment, and methodology by a representative of the department at any time during the laboratory's working hours. The department may accept the on-site inspections of the College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, and other agencies, provided that these agencies have standards that are substantially equal to or more stringent than the requirements of subparts 1 and 2 of this chapter. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110.1-8 Requirements for a class II clinical laboratory permit. (a) A person intending to operate a clinical laboratory may apply for a class II permit if the laboratory:

(1) Is not located in a licensed clinical laboratory;
(2) Is maintained by a licensed medical facility for performing tests solely on the facility's patients;
(3) Performs only waived, PPMP tests, or POCTs or a combination of these tests;
(4) Is certified as a clinical laboratory under 42 C.F.R. part 493 subpart A; and
(5) Remits applicable fees.

(b) A person applying for an initial class II permit or renewal shall complete application forms provided by the department. The application shall include at a minimum:

(1) Name and address of the clinical laboratory where laboratory testing is performed;
(2) Name and address of the owner of the clinical laboratory;
(3) Name of the laboratory director;

(4) Name of the laboratory consultant if the laboratory director is not a clinical laboratory director or medical technologist licensed by the State; and

(5) List of tests and methodologies and approximate annual test volume to be performed by the laboratory.

(c) The laboratory director of a class II clinical laboratory shall:

(1) Be accessible to the laboratory and provide onsite, telephone, or electronic consultation as needed;

(2) Visit the laboratory at least two times per year;

(3) Approve all laboratory tests performed in the laboratory and have written protocols available for all testing personnel;

(4) Prior to patient testing, provide training to testing personnel and document the personnel's competency to perform tests accurately and reliably;

(5) Ensure specimens for laboratory testing are properly collected;

(6) Ensure control materials meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results;

(7) Ensure patient test results are reported accurately and in a timely manner; and

(8) Ensure all federal, state, and county safety regulations are followed.

(d) The laboratory director of a class II clinical laboratory may delegate the laboratory director's duties in writing to the laboratory's laboratory consultant.

(e) The department may inspect the laboratory for initial approval and renewal of a class II permit. A clinical laboratory with a class II permit shall allow the inspection of its premises, records, materials, equipment, and methodology, by a representative of the department at any time during the laboratory's working hours. The department may accept the on-site inspections of the College of American Pathologists, Joint Commission on Accreditation of Healthcare

Organizations, U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, and other agencies, provided that these agencies have standards that are substantially equal to or more stringent than the requirements of this section. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-11.5, 321-13) (Imp: HRS §§321-11, 321.11.5, 321-13)

§11-110.1-9 Requirements for a clinical laboratory license. (a) A person intending to operate a clinical laboratory may apply for a clinical laboratory license if the laboratory:

(1) Is certified as a clinical laboratory under 42 C.F.R. part 493;

(2) Performs moderate or high complexity tests or both, in addition to any combination of waived, PPMPs, or POCTs; and

(3) Remits applicable fees.

(b) A person applying for an initial clinical laboratory license or renewal of a clinical laboratory license shall complete application forms provided by the department and submit the applicable fee. The application shall include at a minimum:

(1) Name and address of the clinical laboratory where clinical laboratory testing is performed;

(2) Name and address of the owner of the clinical laboratory;

(3) Name of the clinical laboratory director licensed by the State;

(4) Names of testing personnel and their Hawaii clinical laboratory personnel license numbers, if required for the laboratory tests they are performing;

(3) A list of tests and methodologies and annual test volume to be performed by the laboratory.

(c) The department may inspect the laboratory for initial approval and renewal of its clinical laboratory license. A licensed clinical laboratory shall allow the inspection of its premises, records, materials, equipment, and methodology, by a representative of the department at any time during the laboratory's working hours. The department may accept the on-site

inspections of the College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services, and other agencies, provided that these agencies have standards that are substantially equal to or more stringent than the requirements of this section. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-11.5, 321-13) (Imp: HRS §§321-11, 321-11.5, 321-13)

§11-110.1-10 Licensed clinical laboratory; clinical laboratory director's responsibilities. (a) The director of a licensed clinical laboratory shall be responsible for:

(1) The technical and scientific operation of the laboratory, including the selection and supervision of test procedures, reporting of results, continuous application of quality control procedures, and active participation in the operations to the extent necessary to assure compliance with the rules and directives of the department;

(2) The proper performance of all tests in the laboratory; and

(3) The technical supervision of qualified laboratory personnel.

(b) Commensurate with the scope and complexity of the services provided, the clinical laboratory director shall ensure that the staff is qualified, sufficient in number, and receives in-service training to maintain competency to perform test procedures and to report test results promptly and proficiently.

(c) If the clinical laboratory director is absent for more than thirty days, the associate clinical laboratory director or, if there is none, a person whose qualifications are satisfactory to the department shall assume the responsibilities of the laboratory director.

(d) When a clinical laboratory director's employment is terminated for any reason, the owner of the clinical laboratory shall notify the department within fourteen days of the termination of employment. [Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110.1-11 Licensed clinical laboratory; personnel requirements. (a) Clinical laboratories shall designate a clinical laboratory director who is licensed by the State, and testing personnel who meet the qualifications and responsibilities set by the laboratory. If so qualified, each individual may serve in more than one position.

(b) Non-licensed clinical laboratory personnel may perform waived, PPMPs, and POCTs. All other laboratory procedures, not including preparatory portions, shall be performed by appropriately licensed clinical laboratory personnel.

(c) An adequate number of qualified personnel shall be provided for the volume and complexity of procedures and tests performed. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110.1-12 Licensed clinical laboratory; specimen identification and examination. (a) Every specimen received for testing shall be labeled and numbered, or otherwise appropriately identified, and listed in an accession log in chronological order.

(b) Every tissue specimen and non-gynecological cytology specimen shall be examined and reported upon by a pathologist who is certified, or eligible for certification, in anatomic pathology by the American Board of Pathology or a physician who has demonstrated to the satisfaction of the department that he or she has the equivalent of such certification.

(c) Every abnormal specimen for exfoliative cytology shall be examined and reported upon by a qualified pathologist.

(d) Initial examination or "screening" of specimens for exfoliative cytology and reporting of negative gynecologic specimens, may be made by a person who is licensed as a cytotechnologist.

(e) Every laboratory shall have a written and documented procedure to assure that an appropriate number of negative gynecological specimens are re-evaluated.

(f) If the component to be tested in a specimen is perishable, labile, or otherwise subject to deterioration, the specimen shall be tested promptly

after collection. If a specimen is transported or stored, it shall be properly preserved, refrigerated, frozen, or otherwise appropriately treated to maintain it in as close to its original state as allowed by current technology.

(g) Every clinical laboratory shall promptly notify the sender of any specimen that is not satisfactory for testing for any reason.

[Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-13 Licensed clinical laboratory; records. (a) Each licensed clinical laboratory shall retain a duplicate copy of the original report made for each specimen received for analysis for at least two years.

(b) Each licensed clinical laboratory shall have a record indicating the daily accession of specimens. The record shall contain the following information:

(1) The laboratory number or other identification of each specimen received by the laboratory;
(2) The name or other unique identification of the person from whom the specimen was taken;
(3) The name of the person or clinical laboratory who submitted the specimen;
(4) If the request for the test was oral and not followed by a written request, a written statement to that effect shall be made;
(5) The date and time, if applicable, the specimen was collected;
(6) The date and time the specimen was received by the clinical laboratory;
(7) If the specimen is forwarded to another laboratory, the name of the other laboratory, the date the specimen was forwarded to the other laboratory, the date it was tested, and the date the report of the findings of the tests was received from the other laboratory;
(8) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed, turbid, etc.);
(9) The actual tests performed;
(10) The results of the laboratory tests or cross reference to results;

(11) The date a report was sent to the department pursuant to section 11-110.1-16(e); and

(12) The name, the initials, or other identification of the person who performed each test, or in the case of a test involving performance by more than one person, the name, the initials, or other identification of the persons who actually supervised the test.

(c) All records and reports of each test performed, including the original or duplicates of original reports from another laboratory, shall be provided to representatives of the department on request. All records shall be retained by the laboratory for a period of at least two years, except for those records or reports that must be retained for a longer period under state or federal law.

(d) Each licensed clinical laboratory shall:

(1) Maintain current personnel records in the clinical laboratory or the personnel office. These records shall include a resume of each employee's training and experience, including dates of previous and current employment, and continuing education; and

(2) Annually submit to the department a list of its clinical laboratory director and testing personnel, including their job titles and license numbers and expiration dates if required for the level of testing the personnel perform. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13) (Imp: HRS §§321-11, 321-13)

§11-110.1-14 Licensed clinical laboratory; proficiency testing and quality assessment programs. (a) Licensed clinical laboratories shall demonstrate to the department proficiency in the performance of the tests offered by the clinical laboratory through state approved proficiency testing programs. The cost of proficiency testing programs shall be borne by the licensed laboratory. All licensed clinical laboratories are required to demonstrate and maintain proficiency in each of the specialties or subspecialties for which it is licensed.

(b) Each licensed clinical laboratory shall maintain a properly documented quality assessment program that is acceptable to the department. The quality assessment program shall be designed to assure, on a continuous basis, the reliability of all laboratory results. All facilities, equipment, and instruments shall have inherent capabilities consistent with the services offered and shall be maintained in good operating condition.

(c) Each licensed clinical laboratory shall maintain a written preventive maintenance program which details periodic inspection for proper operation of each piece of equipment and instrument, a written program for validation and calibration of equipment, a dependable reagent and glassware evaluation system, and a continuous surveillance of results. Appropriate records showing the dates of inspections, validation, evaluation, and significant actions taken in response to revealed defects, shall be maintained.

(d) Current manuals of methods and technical procedures shall be maintained by the laboratory and shall be made available to clinical laboratory personnel and, for inspection, to representatives of the department. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-15 Limitations. (a) A clinical laboratory shall perform only those tests within the limits of its permit or license.

(b) A licensed clinical laboratory shall perform only those tests within the specialties or subspecialties which are stated on its license. The license shall include only those specialties or subspecialties which the clinical laboratory director or testing personnel are qualified to perform. The clinical laboratory director shall notify and seek approval from the department in writing of any changes of specialties or subspecialties at least thirty days prior to the occurrence of each change.

(c) No clinical laboratory license may include the specialty of anatomic pathology or cytology unless tissue specimens or specimens for cytologic examinations are to be examined on the premises by a pathologist or a physician who has demonstrated to the

satisfaction of the department that he or she is qualified by education, training, and experience to perform such procedures pursuant to 42 C.F.R. part 493. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-16 Licensed clinical laboratories and laboratories with class I or class II permits: clinical laboratory procedures. (a) All technical procedures used shall be standard procedures which are generally accepted by authorities in the specialties of laboratory medicine or which are approved by the department. Each technical procedure shall be initially approved, signed, and dated by the laboratory director. Each change in a procedure shall be approved, signed, and dated by the laboratory director.

(b) Except as otherwise provided in this chapter, a clinical laboratory shall examine specimens only at the request of an authorized person.

(c) The result of a test shall be reported only to the authorized person who ordered the test and the designee(s) of the person who ordered the test. No diagnosis or treatment may be made part of the laboratory report, except for reports made by a licensed physician if such reports are signed by the physician.

(d) All specimens accepted by a clinical laboratory shall be tested on its premises. However, specimens for infrequently performed tests, or those not included within its permit or specialties stated on its license, or those requiring specialized equipment and skill, may be forwarded to another laboratory acceptable to the department. The reports of the results of such tests shall be sent by the testing laboratory to the forwarding clinical laboratory. The forwarding laboratory shall send a copy of such reports to the authorized person requesting the test, and shall indicate thereon the name and address of the laboratory in which the test was actually performed.

(e) The clinical laboratory director shall report to the department all laboratory findings which indicate the presumptive presence of any disease required to be reported pursuant to chapter 11-156, entitled "Communicable Diseases," or as required by

other statutes or rules. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-17 Licensed clinical laboratories and laboratories with class I or class II permits: safety and sanitation requirements. (a) All licensed clinical laboratories and laboratories with class I and class II permits shall be maintained and operated in a manner which will not expose employees, patients, or the general public to undue physical, chemical, and biological hazards.

(b) Laboratories shall be well-ventilated, well-lighted, and, if needed for laboratory testing, have a sink with running water and convenient access to gas, suction, or properly grounded electrical outlets. There shall be sufficient space to perform the services provided by the laboratory with optimum accuracy and safety.

(c) All culture processes involving potential sources of aerosolized pathogens shall be performed in a biological safety cabinet. All procedures which involve liberation of toxic, corrosive, or explosive substances shall be performed in a fume hood.

(d) Cylinders of compressed gases shall be secured in a manner to prevent falling or being knocked over.

(e) Blood and blood components used for transfusion shall be stored and maintained at a temperature indicated on the product label. This shall be verified continuously by a recording thermometer and confirmed by a system of audible and visible alarms which are monitored at all times. Stored blood shall be inspected daily.

(f) Flammable or combustible liquids shall be stored in compliance with applicable state and federal standards.

(g) Laboratories using corrosive materials shall have appropriately located safety showers and eye wash stations.

(h) Adequate numbers and appropriate types of fire extinguishers shall be placed in convenient locations, inspected at least annually, and recharged if necessary.

(i) Syringes, needles, lancets, or other blood drawing devices shall be decontaminated and disposed of in compliance with 29 C.F.R. part 1910.1310 and chapter 11-104.1.

(j) Diagnostic use of radioactive isotopes shall conform to the laws of the State and the regulations of the United States Nuclear Regulatory Commission.

(k) Cultures and specimens and all other potentially infectious materials shall be decontaminated in accordance with chapter 11-104.1, prior to disposal.

(l) All personnel handling open specimens shall wear protective clothing and other safety gear as is necessary. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-18 Collecting depot. (a) A clinical laboratory certified under 42 C.F.R. part 493 subpart A may operate collecting depots after first obtaining written approval from the department for the establishment of each depot.

(b) A collecting depot shall:

(1) Have a current, written manual of methods and procedures used to ensure the satisfactory collection of specimens including patient preparation prior to specimen collection, proper specimen identification, and storage and preservation of specimens;

(2) Collect specimens only at the request of authorized persons;

(3) Be adequate for the proper collection of specimens. This shall include adequate and proper staffing, plumbing, heating, cooling, lighting, ventilation, refrigeration, electrical services, sanitary conditions, fire protection within the collecting depot and its surroundings, water supply, sewage disposal, procedures for handling and disposal of specimens, and safety measures for personnel;

(4) Keep and maintain a record indicating the daily accession of specimens. The record shall contain the following information:

(A) The name or other unique identification of the person from whom the specimen was taken;
(B) The name of the person who requested the test;
(C) The date and time when the specimen was received or when it was collected;
(D) Signature or suitable identification of the person receiving or collecting the specimen;
(E) The type or source of the specimen; and
(F) The test(s) requested.

(5) The results of a test shall be reported only to the person described in paragraph(2).

(c) No laboratory tests shall be performed in a collecting depot. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-19 Unlawful practices. (a) A clinical laboratory's permit or license shall not be the subject of sale, assignment, or transfer, voluntary or involuntary, nor shall the license be valid for any location other than that for which it was issued.

(b) No establishment other than a clinical laboratory certified under 42 C.F.R. part 493 subpart A or a collecting depot conducted in conformity with section 11-110.1-18 shall receive specimens for the purpose of laboratory examination to obtain information for diagnosis, prevention, or treatment of a disease or the assessment of a medical condition. Clinical laboratories operating outside the State shall receive clinical specimens collected in the State only at the request of an authorized person. [Eff JUL 05 2007] (Auth: HRS §321-11) (Imp: HRS §321-11)

§11-110.1-20 Violations. (a) If the department determines that any requirements of this subchapter have been violated, the department shall notify the clinical laboratory's laboratory director and owner of the violation in writing by certified mail. In the notice the department shall set forth the specific violations and may do one or more of the following:

(1) Impose fines;

(2) Place restrictions on the permit or license;
(3) Revoke the permit or license;
(4) Establish a specific time for the correction of each correctable violation; and
(5) Approve or disapprove a written plan of correction submitted by the laboratory director for each correctable violation.

(b) If violations are not corrected within the time specified in the notice or in the accepted plan of correction, the department may do one or more of the following:

(1) Impose fines;
(2) Place restrictions on the permit or license, or
(3) Revoke the permit or license.

(c) The permit or license of a clinical laboratory may be revoked, suspended, or denied for violations of the provisions of this chapter, or for one or more of the following reasons:

(1) A false statement made on an application for a permit or license or any other document submitted to the department;
(2) Knowingly permitting unauthorized persons to perform technical procedures or issue or sign reports;
(3) Consistent errors in performance of laboratory procedures, based on faulty technique or controls;
(4) Dishonest reporting of test results;
(5) Knowingly performing a test and rendering a report thereon to a person not authorized by law to submit the specimens;
(6) Failure to make a report of a communicable disease pursuant to section 11-110.1-16(e); and
(7) Any other activity that is detrimental to the public health.

(d) The director may suspend the permit or license of a clinical laboratory to perform tests in one or more of the specialties or subspecialties stated on a license, for a period not to exceed ninety calendar days, pending the final determination of charges against the laboratory, whenever there has been error in the laboratory tests to such a degree that in the opinion of the director it poses an imminent and

substantial danger to the health or life of a patient or member of the public.

(e) A decision to revoke, suspend, restrict, or deny a permit or license shall become final twenty days after the decision was mailed to the laboratory director and owner by certified mail, unless the alleged violator submits a written request for a hearing before the director pursuant to chapter 91, Hawaii Revised Statutes. Upon receipt of the request, the director shall notify the alleged violator of the specific time and location of the hearing.

(f) All written plans of correction shall be submitted to the department within ten calendar days of the department's notification to the laboratory owner or laboratory director of the violation or violations. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13, 321-20) (Imp: HRS §§321-11, 321-13)

§§11-110.1-21 to 22 (Reserved).

SUBCHAPTER 3

CLINICAL LABORATORY PERSONNEL

§11-110.1-23 Clinical laboratory personnel license. (a) No person shall serve as a clinical laboratory director, medical technologist (clinical laboratory scientist), clinical laboratory specialist, cytotechnologist, or medical laboratory technician without a current and valid clinical laboratory personnel license issued by the department.

(b) Application forms for licensure may be obtained by request from the state laboratories division, department of health.

(c) The clinical laboratory personnel licenses are:

(1) Clinical laboratory director;
(2) Medical technologist (clinical laboratory scientist);
(3) Clinical laboratory specialist;
(4) Cytotechnologist; and
(5) Medical laboratory technician (clinical laboratory technician).

(d) Every applicant for a clinical laboratory personnel license shall provide documents verifying education, training, and employment experience requested on the application form.

(e) The specific education, training, and experience requirements for clinical laboratory personnel licenses may be waived by the director if the applicant presents evidence to the satisfaction of the director that the applicant's combination of education, training, and experience is substantially equivalent to the specific clinical licensure requirements.

(f) All applications for original licensure shall be approved or denied no later than sixty calendar days following the date that the application is complete with all required documents verifying education, training, experience and full payment of all required fees. All applications for license renewal or restoration shall be approved or denied no later than sixty calendar days following receipt of a completed renewal or restoration application and the full payment of all required fees.

(g) All clinical laboratory personnel licenses shall expire on January 31 of each odd-numbered year.

(h) All valid clinical laboratory personnel licenses in effect immediately prior to the effective date of this subchapter shall remain in effect until their renewal dates. [Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14, 321-15) (Imp: HRS §§321-13, 321-14, 321-15)

§11-110.1-24 (Reserved).

§11-110.1-25 Clinical laboratory director. A license to practice as a clinical laboratory director may be issued to an applicant who meets one of the following requirements:

(1) Is a physician licensed to practice medicine under HRS chapter 453 or osteopathy under HRS chapter 460 and is:

(A) Certified in anatomical or clinical pathology or in one of the clinical laboratory specialties by the American Board of Pathology or the American

Osteopathic Board of Pathology; or

(B) Certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, or other certifying agency acceptable to the department, in one of the laboratory specialties;

(2) For the subspecialty of oral pathology only, is a physician licensed to practice medicine under HRS chapter 453 or osteopathy under HRS chapter 460 and is certified by the American Board of Oral Pathology, the American Board of Pathology, or the American Osteopathic Board of Pathology;

(3) Holds a doctoral degree from an accredited college or university in a chemical, physical, biological, or clinical laboratory science, and:

(A) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology, or other certifying agency acceptable to the department, in one of the laboratory specialties; and

(B) Has at least two years of pertinent full-time laboratory experience in one or more of the clinical laboratory specialties, including at least one year of clinical laboratory supervisory experience in a laboratory acceptable to the department. [Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14; Imp: HRS §§321-13, 321-14)

§11-110.1-26 Medical technologist (clinical laboratory scientist). A license to practice as a medical technologist (clinical laboratory scientist) may be issued to an applicant who is certified as a medical technologist (clinical laboratory scientist) by

a certifying agency acceptable to the department, and who meets one of the following requirements:

(1) Holds a bachelor's degree in medical technology from an accredited college or university and has successfully completed an accredited program of medical technology;

(2) Holds a bachelor's degree in medical technology from an accredited college or university and has completed one year of full-time experience as a medical laboratory technician in a clinical laboratory acceptable to the department;

(3) Holds a bachelor's degree in a chemical, physical, or biological science from an accredited college or university which includes completing:

(A) Sixteen semester hours in chemistry courses of which at least six semester hours are in introductory college chemistry that are acceptable toward a major in chemistry; and

(B) Sixteen semester hours in biology courses that are pertinent to the clinical laboratory sciences and are acceptable towards a major in the biological sciences; and

(C) Three semester hours in college mathematics; and

has completed one year of full-time clinical laboratory experience that included a minimum of two months each in clinical chemistry, clinical microbiology, hematology, immunology and immunohematology in a laboratory acceptable to the department;

(4) Has successfully completed a minimum of ninety semester hours (or their equivalent) in an accredited college or university and has successfully completed a course of training of at least twelve months in an accredited program of medical technology.

(A) For an applicant who completed training prior to September 15, 1963, the ninety semester hours shall include at least twenty-four semester hours of chemistry and biology courses of which:

(i) At least six semester hours were in introductory college chemistry and at least three semester hours were in other chemistry courses; and

(ii) At least twelve semester hours were in biology courses pertinent to the clinical laboratory sciences; or

(B) For an applicant who completed training after September 14, 1963, the ninety semester hours shall include:

(i) Sixteen semester hours in chemistry courses that include at least six semester hours in introductory college chemistry that are acceptable toward a major in chemistry;

(ii) Sixteen semester hours in biology courses that are pertinent to the clinical laboratory sciences and are acceptable towards a major in the biological sciences; and

(iii) Three semester hours of college level mathematics (see 42 C.F.R. part 493 subpart M).

[Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110.1-27 Clinical laboratory specialist. A license to practice as a clinical laboratory specialist in one of the laboratory specialties may be issued to an applicant who is certified by a certifying agency acceptable to the department, in the laboratory specialty for which licensure is sought and who meets one of the following requirements:

(1) Holds a bachelor's degree in a pertinent chemical, physical, or biological science, as determined by the director, from an accredited college or university and has successfully completed at least one year of pertinent full-time clinical laboratory experience in a laboratory acceptable to the department or one year of training in an accredited program, or both, in the specialty

for which licensure is sought; or

(2) Has successfully completed at least ninety semester hours (or their equivalent) from an accredited college or university and one year of training in a accredited program in the laboratory specialty for which licensure is sought.

(A) An applicant who completed training prior to September 15, 1963 must have twenty-four semester hours in chemistry and biology courses of which:

(i) Six semester hours were in introductory college chemistry and three semester hours were in other chemistry courses; and

(ii) Twelve semester hours were in biology courses pertinent to the clinical laboratory specialty for which licensure is sought;

(B) An applicant who completed training after September 14, 1963 needs:

(i) Sixteen semester hours in chemistry courses that includes six semester hours in introductory college chemistry that are acceptable towards a major in chemistry;

(ii) Sixteen semester hours in biology courses that are pertinent to the clinical laboratory specialty for which licensure is sought and are acceptable towards a major in the specialty; and

(iii) Three semester hours of college level mathematics (see 42 C.F.R. part 493 subpart M).

[Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§11-110.1-28 Cytotechnologist. A license to practice as a cytotechnologist may be issued to an applicant who is certified in cytotechnology by a certifying agency acceptable to the department, and who has met one of the following requirements:

(1) Holds a bachelor's degree in cytotechnology from an accredited college or university;
(2) Holds a bachelor's degree in a chemical, physical, or biological science and has successfully completed an accredited program in cytotechnology;
(3) Before September 1, 1992, has successfully completed at least sixty semester hours (or their equivalent) in an accredited college or university with at least twelve semester hours in science, eight of which are in biology; and:
    (A) Completed twelve months of training in an accredited program of cytotechnology; or
    (B) Completed six months of formal training in an accredited program of cytotechnology and six months of full-time experience in a clinical laboratory under the direct supervision of a pathologist who is certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology;
(4) Before September 1, 1994, has full-time experience of at least two years within the preceding five years examining slide preparations under the supervision of a pathologist who is certified in anatomic pathology by the American Board of Pathology of the American Osteopathic Board of Pathology or other physician certified as a specialist in cytology, and before January 1, 1969, must have:
    (A) Graduated from high school; and
    (B) Completed six months of training in cytotechnology in a laboratory that is acceptable to the department and was directed by a pathologist or other physician certified as a specialist in cytology (see 42 C.F.R. part 493 subpart M). [Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13, 321-14)

§§11-110.1-29 to 30 (Reserved).

§11-110.1-31 Medical laboratory technician (clinical laboratory technician). A license to practice as a medical laboratory technician may be issued to an applicant who is certified as a medical laboratory technician or a medical technologist by a certifying agency acceptable to the department, and who has met one of the following qualifications:

(1) Holds an associate degree from an accredited program for medical laboratory technicians;

(2) Has successfully completed at least sixty semester hours (or their equivalent) which included courses in chemistry and biology from an accredited college or university and has either of the following:

(A) Completed an accredited program for medical laboratory technicians; or

(B) Completed an advanced military medical laboratory technician course in the United States Armed Forces of at least fifty weeks duration and held the military enlisted occupational specialty of Medical Laboratory Specialist (laboratory technician) within the five years immediately prior to date of application for licensure.

(3) Has successfully completed at least sixty semester hours (or their equivalent) which included courses in chemistry and biology from an accredited college or university and is certified as a medical technologist or a medical laboratory technician after passing a written examination by a foreign certifying agency of clinical laboratory personnel.

[Eff JUL 05 2007] (Auth: HRS §§321-13, 321-14) (Imp: HRS §§321-13. 321-14)

§11-110.1-32 (Reserved).

§11-110.1-33 Exemptions. Any new clinical laboratory personnel licensing requirement that is added by this subchapter shall not be a bar to the license renewal of any person who held a clinical laboratory personnel license immediately prior to the effective date of this subchapter. [Eff JUL 05 2007]
(Auth: HRS §321-13)(Imp: HRS §321-13)

§11-110.1-34 Revocation, suspension, limitation, or denial of a clinical laboratory personnel license. (a) A clinical laboratory personnel license may be revoked, suspended, limited, or denied for one or more of the following reasons:

(1) A false statement or material omission made on an application for licensure or license renewal or on any other document submitted to the department;
(2) False reporting or knowingly permitting false reporting of test results;
(3) Conviction, whether by nolo contendere or otherwise, of a felony or any penal offense substantially related to the qualifications, functions, or duties of clinical laboratory personnel under the laws of any state of the United States or of the federal government. The record of conviction or a certified copy thereof shall be conclusive evidence of such conviction;
(4) Allowing unauthorized persons or unqualified persons to perform technical laboratory procedures or to issue or to sign reports;
(5) Excessive number of errors in the results of tests performed, supervised, or directed by the licensee;
(6) Performing a test and rendering a report thereon to a person who is not an authorized person;
(7) Any conduct that poses an immediate and serious threat to patient health and safety, including performing or supervising laboratory tests which the licensee is unqualified to supervise or to perform;

(8) Being habituated to the excessive use of drugs or alcohol; or being addicted to, dependent on, or a habitual user of a narcotic, barbiturate, amphetamine, hallucinogen, or other drug having similar effects;

(9) Practicing in a clinical laboratory while the ability to practice is impaired by alcohol, drugs, or mental instability;

(10) Violation of Child Support Enforcement, chapter 576D, HRS; or

(11) Revocation, suspension, or any other disciplinary action by another state of a license or certificate for reasons as provided in this subsection or any disciplinary action of a practice privilege by any agency of the United States.

(b) The director of health may summarily suspend a person's clinical laboratory personnel license for a period not to exceed thirty working days for the following conditions:

(1) Pending the final determination of charges against the licensee that there has been an error in the results of tests performed by the licensee or under the supervision of the licensee to such a degree that the director of health finds it poses an imminent and substantial danger to the health or life of a patient or members of the public; or

(2) When the conduct of the licensee poses an imminent and substantial danger to the health or life of a patient or the public.

(c) A clinical laboratory personnel license shall be suspended or denied whenever the Child Support Enforcement Agency issues a certification of noncompliance for license suspension or denial pursuant to section 576D-13, HRS. The clinical laboratory personnel license shall be restored or may be granted after the Child Support Enforcement Agency issues an authorization to release license suspension or denial.

(d) A clinical laboratory personnel license shall not be renewed or reinstated and shall be denied or suspended when the department receives certification pursuant to chapter 436C, HRS.

(e) An applicant whose clinical laboratory personnel license is revoked, suspended, limited, or denied shall be entitled to an administrative hearing pursuant to chapter 91, HRS. [Eff JUL 05 2007] (Auth: HRS §§321-11, 321-13; SLH 1997, Act 293) (Imp: HRS §§91-13.1, 321-11, 321-13, 321-15, 321-20)

§11-110.1-35 (Reserved).

§11-110.1-36 Fees. (a) The department shall not issue an original license or renew a license without first collecting the appropriate fee:

(1) Non-refundable application fees for licenses:

(A)	Clinical laboratory director	$25
(B)	Medical technologist	$25
(C)	Clinical laboratory specialist	$25
(D)	Cytotechnologist	$25
(E)	Medical laboratory technician	$25

(2) License fee:

(A)	Clinical laboratory director	$50
(B)	Medical technologist	$40
(C)	Clinical laboratory specialist	$40
(D)	Cytotechnologist	$40
(E)	Medical laboratory technician	$40

(3) License renewal fee:

(A)	Clinical laboratory director	$40
(B)	Medical technologist	$30
(C)	Clinical laboratory specialist	$30
(D)	Cytotechnologist	$30
(E)	Medical laboratory technician	$30

(4) Restoration fee: $20

(b) All fees shall be collected by the department at the time of application for initial licensure, license renewal, and restoration of license.

(c) Requests for license renewal and the renewal fees must be received by the department by January 31 of each odd-numbered year starting in the year 2003. The failure, neglect, or refusal of any person holding such license to request renewal or to pay the renewal fee after thirty days of delinquency shall constitute a forfeiture of the person's license; provided that a forfeited license may be restored upon written application and payment of all delinquent fees. If a

license is forfeited for one year and less than two years, the department may request that the applicant submit additional information and evidence satisfactory to the department, including passing of an examination, or showing that the applicant remains fit to practice as a clinical laboratory personnel, or both before the license is restored. A license that has been forfeited for two years or more shall not be restored and a new application for license shall be required.

(d) A fee shall be paid for the restoration of a license suspended pursuant to chapter 436C, HRS, or pursuant to chapter 576D, HRS. [Eff JUL 05 2007] (Auth: HRS §§321-11.5, 321-14, 321-15) (Imp: HRS §§321-14, 321-15)

§11-110.1-37 Violations. Anyone who violates any provision of this subchapter may be fined not more than $1000 for each day of violation, may be subject to revocation, suspension, restriction, or limitation of licensure or to any other remedies or provisions of §§ 321-15 and 321-20, HRS, and may have recourse to an administrative hearing in accordance with chapter 91, HRS, and the department's rules of practice and procedure. [Eff JUL 05 2007] (Auth: HRS §§321-13, 321-20) (Imp: HRS §§321-11, 321-13, 321-20)